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APPLICATION TEAM PROGRAM

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*Applications of Aerospace Technology
in
Biology and Medicine*

semi-annual report

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**RESEARCH TRIANGLE INSTITUTE
RESEARCH TRIANGLE PARK, NORTH CAROLINA**

PREFACE

This report covers the medically related activities of the NASA Application Team Program at the Research Triangle Institute between September 1, 1972, and February 28, 1973, performed in accomplishing NASA Contract NASW-2459. This work was performed in the Center for Technology Applications of the Research Triangle Institute under the technical direction of Dr. J. N. Brown, Director. Full-time members of the Team who participated in the project are Dr. F. T. Wooten, Director of the Application Team; Mr. Ernest Harrison, Jr.; Mr. E. W. Page; Mr. R. W. Searce; and Ms. Jackie Manning. Assistance from other members of the RTI staff was obtained as needed.

Medical consultants who contributed significantly to the project are Dr. E. A. Johnson, Duke University Medical Center, Durham, North Carolina; Dr. George S. Malindzak, Jr., Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, North Carolina; Mr. William Z. Penland, National Cancer Institute, Bethesda, Maryland; Professor Hal C. Becker, Tulane University School of Medicine, New Orleans, Louisiana; Dr. Jacob Kline, University of Miami School of Medicine, Miami, Florida; and Mr. Edward Wallerstein, Mount Sinai Medical Center, New York, New York.

For the convenience of the reader, the names and addresses of the sources of commercial products are included in this report. This listing does not constitute an endorsement by either the National Aeronautics and Space Administration or the Research Triangle Institute.

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ABSTRACT

This report presents the results of the medically related activities of the NASA Application Team Program at the Research Triangle Institute. This experimental program in technology application was supported by NASA Contract No. NASW-2459 for the reporting period September 1, 1972, to February 28, 1973. The RTI Team is a multidisciplinary team of scientists and engineers acting as an information and technology interface between NASA and individuals, institutions, and agencies involved in biomedical research and clinical medicine. During the reporting period, participants in the Application Team Program included Dr. J. N. Brown, Jr., Electrical Engineer; Dr. F. T. Wooten, Electrical Engineer; Mr. Ernest Harrison, Materials Scientist; Mr. E. W. Page, Electrical Engineer; Mr. R. W. Searce, Biomedical Engineer; and Ms. Jackie Manning. In addition, the Team draws upon the capabilities of other members of the RTI staff as needed.

Fourteen medical organizations are presently participating in the RTI Application Team Program: Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, North Carolina; Duke University Medical Center, Durham, North Carolina; Emory University School of Medicine, Atlanta, Georgia; Medical University of South Carolina, Charleston, South Carolina; Mount Sinai Medical Center, New York, New York; National Cancer Institute, Bethesda, Maryland; National Heart and Lung Institute, Bethesda, Maryland; National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina; Ochsner Clinic and Foundation, New Orleans, Louisiana; Tulane University School of Medicine, New Orleans, Louisiana; University of Miami School of Medicine, Miami, Florida; University of North Carolina Dental School and Dental Research Center, Chapel Hill, North Carolina; University of North Carolina School of Medicine, Chapel Hill, North Carolina; and Virginia Department of Vocational Rehabilitation, Fishersville, Virginia.

The accomplishments of the Research Triangle Institute Application Team during the reporting period are as follows: The Team has identified 21 new problems for investigation, has accomplished 4 technology applications and 3 potential technology applications, has closed 21 old problems, and on February 28, 1973, has a total of 57 problems under active investigation.

1.0 PROGRAM PHILOSOPHY AND METHODOLOGY

1.1 Introductory Comments

The National Aeronautics and Space Administration (NASA) has been a leader and innovator in the establishment, operation, and assessment of technology transfer programs since that agency was established by the Space Act of 1958. Through its Tech Brief, Special Publication, Technology Survey, and Regional Dissemination Center programs, NASA has been successful in transferring the results of aerospace research to an impressive number of nonaerospace applications.

In 1966, NASA established a program using an active and directed methodology. In this program, Application Teams were established under contract to the NASA Technology Utilization Office. The Application Team methodology is active in that specific problems are identified and specified through direct contact with potential users of aerospace technology. The process is directed in that teams interact only with potential users who are involved in reaching selected national goals. Three teams concentrate in the biomedical area while others work in such fields as air pollution control, water pollution control, transportation, mine safety, and law enforcement. The three teams specializing in biomedicine have been established at the following institutions:

Research Triangle Institute
Post Office Box 12194
Research Triangle Park, North Carolina 27709

Southwest Research Institute
8500 Culebra Road
San Antonio, Texas 78228

Stanford University School of Medicine
701 Welch Road
Palo Alto, California 94304

This report covers the accomplishments and activities of the Team located at the Research Triangle Institute for the period September 1, 1972, to February 28, 1973. In the remainder of Section 1.0, Team objectives and methodology are presented.

1.2 Application Team Program

The NASA Application Team Program specifically seeks to achieve the following goals:

- (a) The identification of relevant aerospace technology that can solve major medical problems;
- (b) The utilization of the identified technology in order to actually solve the existing medical problems; and
- (c) The motivation of members of the industrial community to manufacture technology resulting from this program in order that widest possible use of the technology can be achieved.

Basically, the Team acts as an active interface between medical investigators and the body of scientific and technical knowledge that has resulted from this Nation's aerospace research program. The Team attempts to carefully define the technological problems facing the medical community and to identify the relevant aerospace technology that can solve those problems. The problems are those being encountered in medical research programs in major medical schools and in the National Institutes of Health. The Team actively engages in the identification of these problems through direct contacts with the medical research staffs; the identification and specification of the medical problems is then followed by search for technology that can be utilized in solution of the problem.

Generally, technology relevant to specific problems is identified through three approaches: (1) manual and computer searching of the aerospace information bank created by NASA as part of its R&D effort, (2) direct contact with the engineering and scientific staff at NASA Field Centers, and (3) circulation of concise problem statements to a large number of NASA scientists and engineers. Technology representing potential solutions to problems is channeled through the Team to the problem originator for evaluation and implementation as a solution to his problem. Alternatively, and with increasing frequency, the Team establishes a contact between the problem originator and NASA Field Center personnel, and the transfer of information between NASA and the medical field becomes more direct.

Assistance to the problem originator in implementing solutions to problems is an important part of the Application Team Program. This assistance may take any one of a number of different forms. Direct assistance to the problem originator in his efforts to implement a solution is frequently involved. During this reporting period, NASA's

Technology Utilization Division has utilized reengineering or adaptive engineering facilities of various NASA centers in those cases where feasibility had to be demonstrated. The Teams are responsible for identifying the NASA technology that is potentially a solution to a specific problem and for specifying the changes required in this technology. The adaptive engineering activity allows the Teams to demonstrate that the technology is in fact a solution to the problem and allows the problem originator to make use of the NASA technology in his research that might otherwise be impossible.

The successful transfer of information on aerospace technology to an individual or group in the medical field followed by successful implementation of the technology with resulting benefits to the accomplishment of some medical objective is called a "technology application." Also included in the definition of technology application is the constraint that the medical application and objective involved in the technology application be different from the aerospace application and objective for which the technology was originally developed. Thus, the accomplishment of technology applications is indeed a difficult and long-term objective. This objective should be distinguished from that involved in a program to enhance the diffusion or broad utilization of demonstrated applications of technology. The transfer of technology involves crossing what may be thought of as an "application or objective barrier," and it involves complete evaluation of the new application; diffusion involves neither of these requirements.

A specific methodology is applied by the Team in its efforts to effect applications of aerospace-related technology. This methodology is discussed in the following section.

1.3 Methodology

The methodology used by the Team consists of five basic steps: problem definition, identification of relevant technology, evaluation of relevant technology, utilization of technology, and documentation. This methodology can be better understood, however, if it is separated into the steps shown in Figure 1. These steps are described in the following paragraphs.

Problem Screening - Effective problem screening is at least as important to the success of the Application Team Program as any of the operational steps identified in Figure 1. Analysis of the RTI Team's accomplishments in the early days of the program indicates clearly that a very significant fraction of the problems that were investigated unsuccessfully could have been rejected very early in discussions with problem originators. Problem selection criteria have since been developed with the objective being to increase the probability that a technology application can be accomplished for those problems accepted by the Team. At the present the following criteria are being applied:

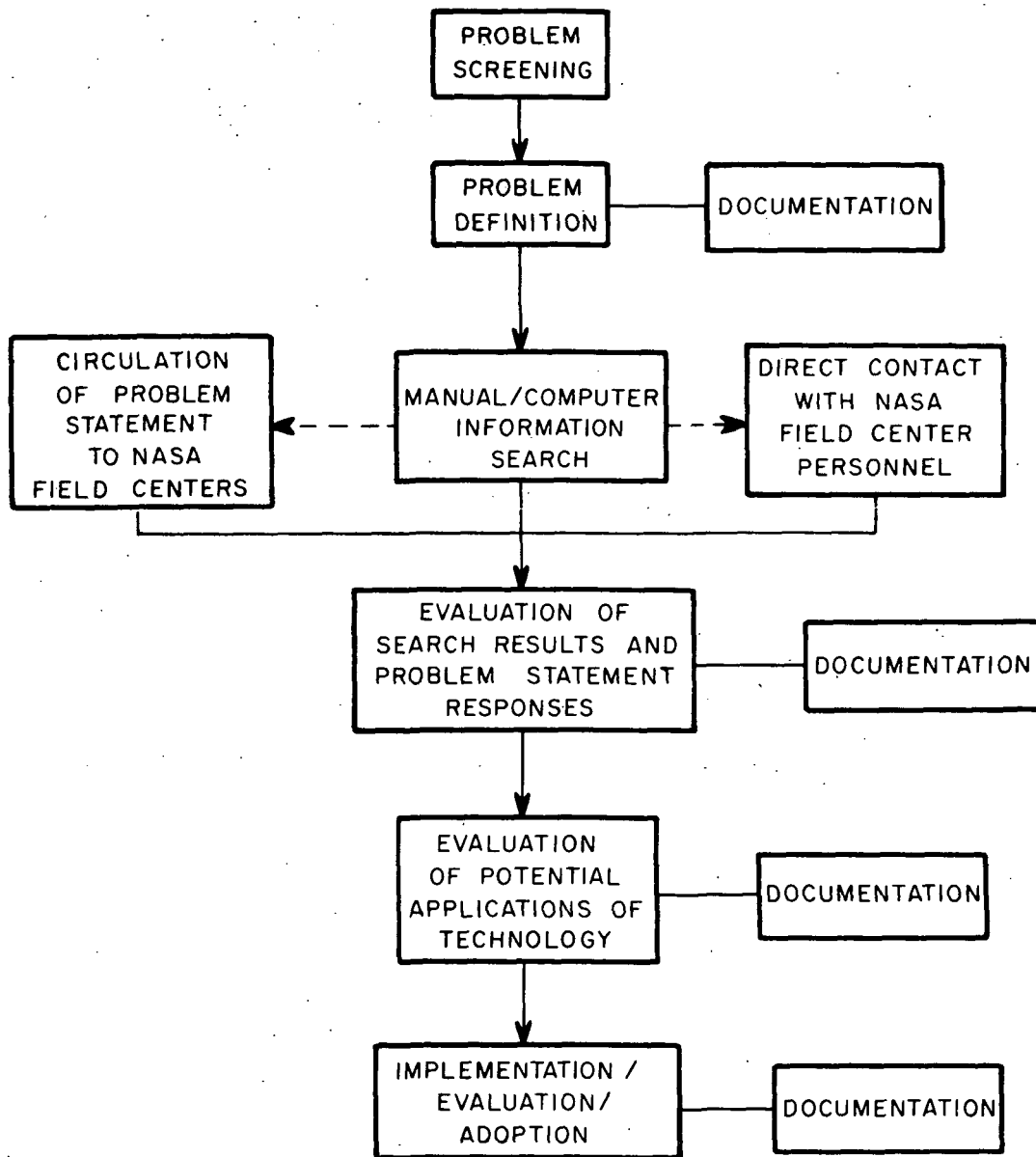


Figure 1. Flow Chart of Application Team Transfer Methodology.

- (a) Solving the problem would enhance medical diagnosis, treatment, or patient care to the extent that implementation and adoption would be rapid.

OR

- (b) The problem has been encountered in an ongoing research program and is impeding progress of that program.

OR

- (c) Either some unique characteristics of the problem or the problem originator indicates that investigating the problem will enhance the overall Team program.

AND

- (d) Solving the problem is given high priority by the problem originator.

AND

- (e) The problem is one of *at most* two being investigated with an individual problem originator. (This is violated only in the case of large group efforts.)

Problems that do not satisfy these criteria are rejected. Problems may also be rejected following partial completion of the next step, problem definition.

Problem Definition - The objective of this step is to define precisely and accurately the characteristics of the technology required to solve a problem. In many cases, following the characterization of required technology, it is found that the problem should be rejected or closed for any of a number of reasons. These reasons include, as examples, the following: (1) the problem can be solved using commercially available equipment; (2) the problem cannot be solved, so that an entirely different approach is indicated; (3) the real problem is medical and not technical in nature; and (4) the requirements cannot be specified because insufficient information exists on the objective involved.

The end result of problem definition is the preparation of a problem statement. This statement, to be complete, must contain (1) a complete characterization of what is required to solve the problem, and (2) the related medical problem or objective and the benefits to be realized by solving the problem.

Identification of Relevant Aerospace Technology - Aerospace technology that may be relevant to the solution of a problem is identified by

three approaches. First, a manual or computer search is made of the aerospace information bank. These searches are made at one of NASA's six Regional Dissemination Centers (RDC). The RDC used by the RTI Team is the North Carolina Science and Technology Research Center (NCSTRC) located in Research Triangle Park, North Carolina. In addition, searches are made utilizing the NASA Scientific and Technical Information Facility in College Park, Maryland. The information that can be assessed through the information bank consists of approximately 700,000 documents, articles, and translations that have been abstracted in the Scientific and Technical Aerospace Reports (STAR) and the International Aerospace Abstracts (IAA). Second, the Team contacts individuals at the Field Centers directly without circulating problem statements. This is done when a Team member can identify a relatively few individuals at the Field Centers who are likely to have a good overview of all work being done that is related to the requirements of a specific problem. Third, problem statements are circulated to engineers and scientists at NASA Field Centers who may be able to identify relevant technology and suggest possible solutions to problems. These statements are circulated in a highly selective manner with the distribution being determined by the Team, Technology Utilization Officers (TUO) at the NASA Field Centers, and other individuals at the Field Centers.

Evaluation - All potentially relevant technology identified in the preceding step is evaluated by the Team to determine whether a potential solution to a specific problem has been found. Those items of technology that represent potential solutions to problems are presented to problem originators along with available supporting data and information. Any required reengineering and details of implementing the potential solutions are discussed with the problem originator.

The problem originator must then evaluate potential solutions. His decision to implement a proposed solution will depend upon a number of factors: (1) his assessment of the validity of the proposed potential solution, (2) the cost of implementing the potential solution, (3) the potential benefits to be gained, etc. The Team may be asked to supply additional information and technical details in this evaluation.

Implementation, Final Evaluation, Adoption - The final step in the technology application process is the implementation and the experimental evaluation of potential solutions. This critical phase must occur in order for a technology application to be complete. The team is available for assistance in this step when required, and attempts to identify the resources necessary to meet the implementation requirements. In many cases the actual implementation can be carried out by the problem originator and his staff. In some cases, however, skills not immediately available to the problem originator are required for implementation and, in these cases, some other resource is utilized. This may require the use of a NASA capability at one of the Field Centers or at a NASA contractor. In other cases the implementation may be carried out by an industrial concern under contract to the problem originator. In general, the team attempts to determine the most appropriate means of implementation and to make recommendations to the problem originator as required.

Documentation - Documentation is an integral part of the Team methodology; it is involved at most steps in the process, as indicated in Figure 1. Documentation allows analysis of the technology application process and assessment of the program in general. At present, the Teams report on a weekly, monthly, and semiannual schedule. Effective communication is required between Teams, potential problem originators, and other individuals who are in a position to make use of information resulting from technology applications accomplished by the Teams.

1.4 Application Team Composition and Participating Medical Institutions

The RTI Team is a multidisciplinary group of engineers and scientists. The educational backgrounds of the group are in physics and electrical engineering; their experience includes industry, education, and research at both basic and applied levels. The individuals who have participated in the Application Team Program during this reporting period are:

<i>Name</i>	<i>Background</i>	<i>Responsibility</i>
Dr. J. N. Brown, Jr.	Electrical Engineer	Laboratory Supervisor
Dr. F. T. Wooten	Electrical Engineer	Team Director
Mr. E. Harrison, Jr.	Materials Scientist	Solution Specialist
Mr. E. W. Page	Electrical Engineer	Solution Specialist
Mr. R. W. Searce	Biomedical Engineer	Solution Specialist
Ms. Jackie Manning	Secretary	Documentation

The experience and special capabilities of other individuals at RTI--particularly in the Engineering and Environmental Sciences Division--are frequently used as needed in the Application Team Program.

At present, 14 medical institutions are participating in the RTI Application Team Program. These institutions are as follows:

Bowman Gray School of Medicine, Wake Forest University,
Winston-Salem, North Carolina;

Duke University Medical Center, Durham, North Carolina;
(Including Veterans Administration Hospital, Durham, North
Carolina);

Emory University School of Medicine, Atlanta, Georgia;

Medical University of South Carolina, Charleston, South Carolina;

Mount Sinai Medical Center, New York, New York;

National Cancer Institute, Bethesda, Maryland;

National Heart and Lung Institute, Bethesda, Maryland;

National Institute of Environmental Health Sciences, Research
Triangle Park, North Carolina;

Ochsner Clinic and Foundation, New Orleans, Louisiana;

Tulane University School of Medicine, New Orleans, Louisiana;

University of Miami School of Medicine, Miami, Florida;
(Including Veterans Administration Hospital, Miami, Florida);

University of North Carolina Dental School and Dental Research
Center, Chapel Hill, North Carolina;

University of North Carolina School of Medicine, Chapel Hill,
North Carolina;

Virginia Department of Vocational Rehabilitation, Fishersville,
Virginia.

Figure 2 shows the geographical distribution of the RTI Application Team
user institutions as well as the location of the major NASA resources.

The RTI Team is assisted at various stages of the technology application
process by consultants who are on the medical staffs at participating institu-
tions. These consultants or communicators coordinate Team activities at their
institutions and assist Team members primarily in problem definition and eval-
uation of potential solutions. At present, the following individuals are
consultants to the RTI Team.

<i>Name</i>	<i>Specialty</i>
Dr. E. A. Johnson Duke University Medical Center	Cardiac Physiology
Dr. George S. Malindzak, Jr. Bowman Gray School of Medicine, Wake Forest University	Physiology
Professor Hal C. Becker Tulane University School of Medicine	Radiology
Mr. William Z. Penland National Cancer Institute	Engineering
Dr. Jacob Kline University of Miami School of Medicine	Engineering
Mr. Edward Wallerstein Mount Sinai Medical Center	Engineering

Problems at each institution are coded by a letter and number symbol
(e.g., DU-49); the coding for each institution or special problem area
is as follows:

CP - Computer software-type problem
DU - Duke University Medical Center

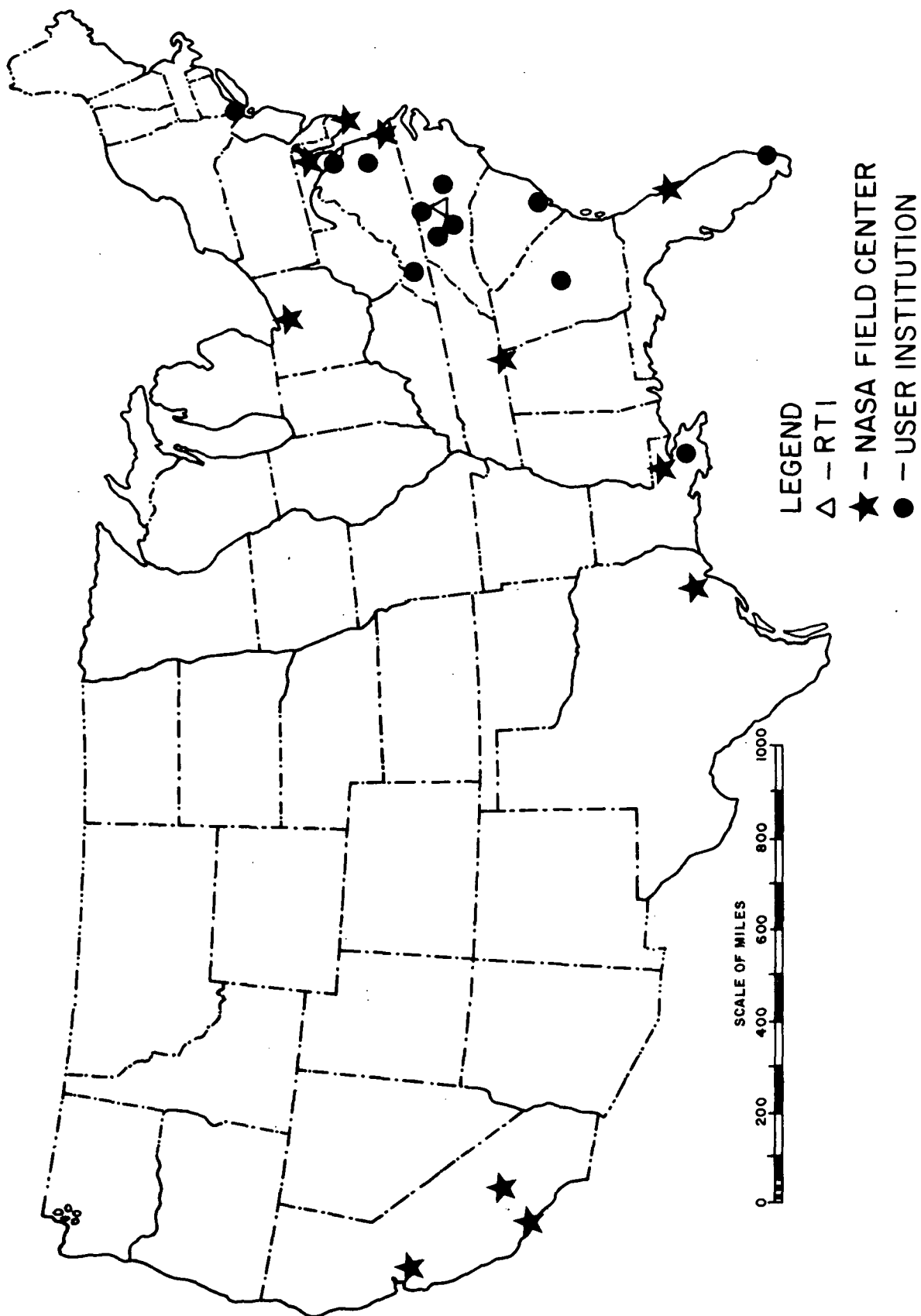


Figure 2. Team Activity Centers in the United States

EU - Emory University School of Medicine
 MISC - Miscellaneous
 MS - Mount Sinai Medical Center
 MUSC - Medical University of South Carolina
 NCI - National Cancer Institute
 NEHSC - National Institute of Environmental Health Sciences
 NHLI - National Heart and Lung Institute
 OF - Ochsner Clinic and Foundation
 TU - Tulane University School of Medicine
 UNC - University of North Carolina School of Medicine
 UNCD - University of North Carolina Dental School and
 Dental Research Center
 VAM - University of Miami School of Medicine
 WF - Bowman Gray School of Medicine, Wake Forest University

1.5 Definition of Terms

In the Application Team Program, a number of terms have evolved that describe the elements and processes in this program. Because of their number and unfamiliarity to many readers, these terms are listed and defined in this section for reference.

Problem Originator or Researcher - An individual actively involved in an effort to reach a specific objective in biology or medicine and faced with a specific technological problem that is impeding progress toward that objective.

Participating Institution - A medically oriented educational institution, hospital, medical center, or government agency having as one of its organization objectives the improvement of medical health care.

Consultant - A member of the biomedical staff at a participating user institution who has committed a portion of his activities to assist the Team in identifying appropriate problem originators at his institution, in understanding and specifying problems in biology and medicine, and in evaluating technological solutions to problems.

Application Team (Team) - A multidisciplinary group of engineers and scientists engaged in problem-solving activities in medicine with the specific objective of effecting the transfer of aerospace technology to solve problems in medicine. The methodology used by the Team involves (1) problem selection, definition, and specification; (2) identification of potential solutions to problems by manual and computer information searching, circulation of problem statements to NASA Field Centers, and contacts with NASA engineers and scientists; (3) evaluation of potential solutions; (4) implementation and adoption by problem originators of aerospace technology as solutions or partial solutions to medical problems; and (5) documentation.

Problem - A specific and definable technological requirement that cannot be satisfied by commercially available equipment or by application of information available to the problem originator through routinely used information channels.

Technology Application - This is the implementation and adoption of aerospace technology that solves a problem in biology or medicine. The medical application involved is one that is different from that application for which the aerospace technology was originally developed.

Problem Statement - This is a concise, written statement of a problem used for communicating (1) sufficient details to allow a computer search to be performed by the information search specialists, and (2) sufficient information to enable NASA engineers and scientists to consider possible solutions to the problem.

Computer Information Search - This is a computerized information search of the aerospace information bank established by NASA and made available through six Regional Dissemination Centers in the United States. This information bank consists of the approximately 700,000 documents that have been indexed and abstracted in the Scientific and Technical Aerospace Reports (STAR) and International Aerospace Abstracts (IAA).

Impact - Information is given to a problem originator with the result that he changes his activities in a way that enhances his progress toward a medical objective. An impact is thus analogous to a technology application except that one or more of the requirements for a technology application are not satisfied.

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2.0 TECHNOLOGY APPLICATIONS, POTENTIAL TECHNOLOGY APPLICATIONS, AND IMPACTS

2.1 Technology Applications

During the reporting period, four applications of aerospace technology were accomplished and are discussed in the following summaries:

PROBLEM TU-3 *Lung Sound Detection*

A technique developed for aerospace vibration and engine-sound analysis has been successfully applied in the analysis of respiratory disease in children.

The major cause of illness in children from infancy through adolescence is respiratory disease of which the more serious forms include asthma, cystic fibrosis, and bronchitis. Significant research is being conducted both in the causes and cures of respiratory diseases and in better methods of diagnosis of the diseases. This problem statement is devoted to finding a method of improved diagnosis that will improve the treatment of respiratory diseases.

The respiratory system consists of the lungs and the system of tubes or ducts that feed air into the lungs. Air proceeds from the nose and mouth through the trachea which is the central air duct. From this central tube, two branches diverge that eventually subdivide still further into smaller tubes called bronchial tubes. Each bronchial tube feeds air into and out of a section of the lung, and each tube has a symmetrical counterpart in the other lung.

One useful and simple method to determine whether a portion of the lung is performing properly is to listen to the sounds made by airflow. Usually this is done with a stethoscope, but only one section of the lung can be heard at a time. To compare sections of the lung, it would be useful to be able to compare the sounds generated by a section of the lung with the sounds generated by the symmetrical counterpart in the other lung.

The basic problem is to detect the sounds from two sections of the chest wall by microphones and to display the sounds graphically. Comparison must be made on the amplitude, frequency, and time interval between appearance of the two sounds.

The frequencies of interest are 50-15,000 Hertz. Breathing rates normally are 25 breaths/minute although a range of 12 to 80 occur. The amplitude of the sounds of interest is not known. Measurements are made on children from infancy to adolescence in a hospital clinic.

In the basic description of the problem, the problem originator desired simply a strip chart recorder and microphone combination. However, the Team advised him that far more information could be gained by using spectral analysis such as that used in analyzing aircraft engines. One difficulty in spectral analysis is that real time spectral analysis is required because of the rapidly changing information in lung sound. Thus, a simple scanning-filter spectral analysis technique was insufficient because of the time response required. A computer search of the NASA document file revealed that NASA had done considerable work in spectral analysis--particularly as pertains to aircraft engines analysis and vibration analysis for vibration testing of spacecraft. The Team proposed to the physician a system (See Figure 3) composed of a microphone, amplifier, and envelope detector which could be fed to a dual-channel strip chart recorder. This dual-channel system would allow time delay measurement for respiratory sounds between similar lobes. In addition, the output of the amplifier could be fed into a spectral analyzer similar to that used in aerospace applications.

The problem originator discussed a joint investigation with the NASA contractor who supplies the spectral analysis equipment. The contractor agreed to furnish the equipment at a fraction of the normal cost: in return, the problem originator provided the medical consultation necessary to develop this new product.

The system was assembled and has been used in a clinical environment for 2 years. A typical analysis of pulmonary sounds is shown in Figures 4 and 5. The results have shown that the frequency range of pulmonary sounds are much higher than had been originally reported. In addition, it was shown that a diseased lung and a normal lung exhibited different spectral analysis patterns for the pulmonary sound. The results of this technology application were presented at the Conference on Engineering and Medicine in Biology, held October 1-5, 1972, in Miami.

The Team feels that this technology application has significance in several areas of pulmonary medicine. First, it is clear that the technique is useful as a diagnostic technique, in order to obtain data not available with a stethoscope. In addition, the technique allows the storage of pulmonary sound data in a convenient mode (photograph) and thus allows a convenient means to evaluate the effects of therapy. The technique also has significance as a teaching function by helping medical students learn more about the nature of pulmonary sounds. In addition, the technique offers the potential for learning more about the basic nature of pulmonary physiology.

This research project is continuing at the Tulane University School of Medicine and future research will determine the breadth of application of the technique in clinical medicine. The availability of commercial equipment for this task will enhance the spread of the use of this new technique.

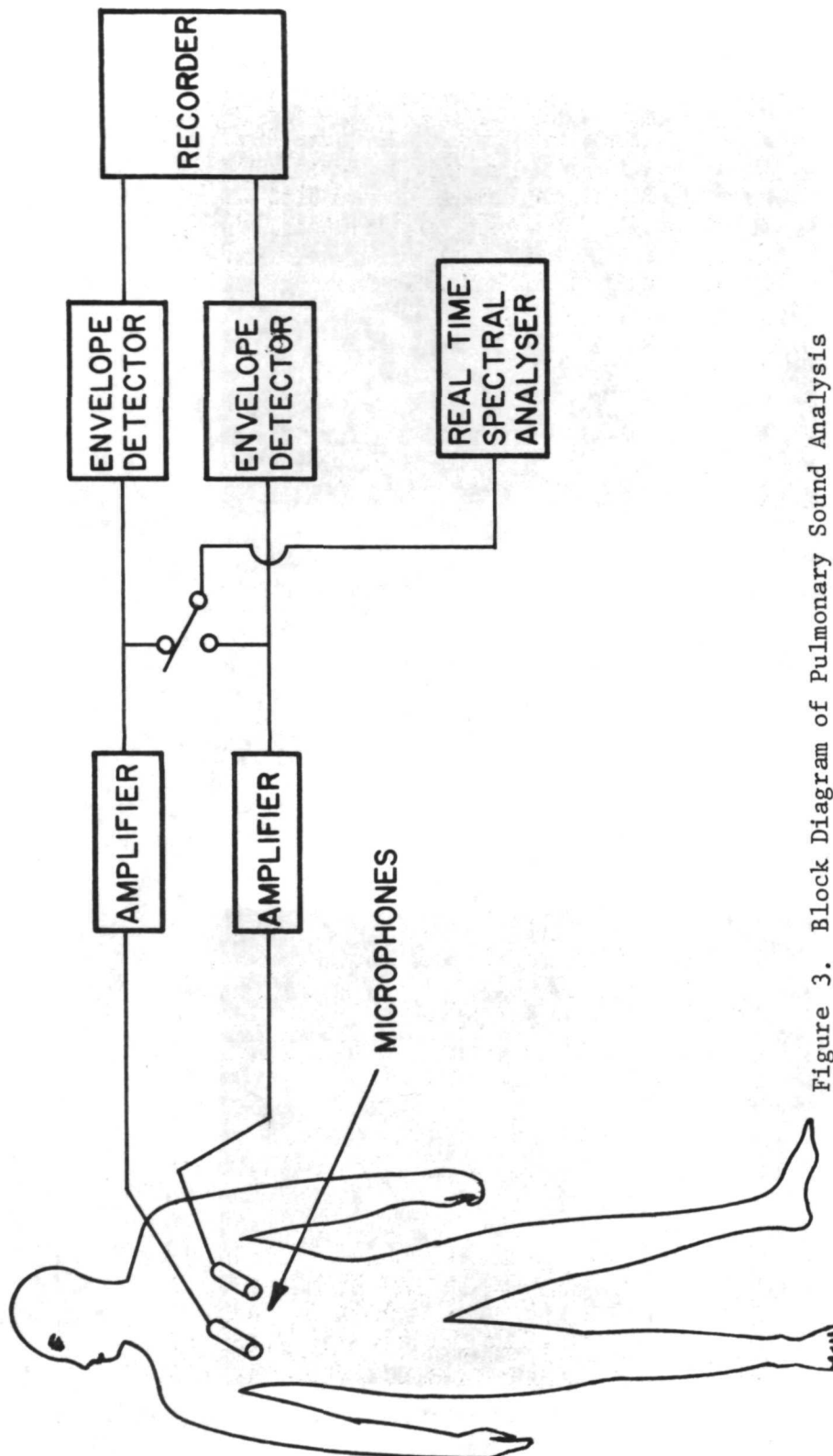


Figure 3. Block Diagram of Pulmonary Sound Analysis System.

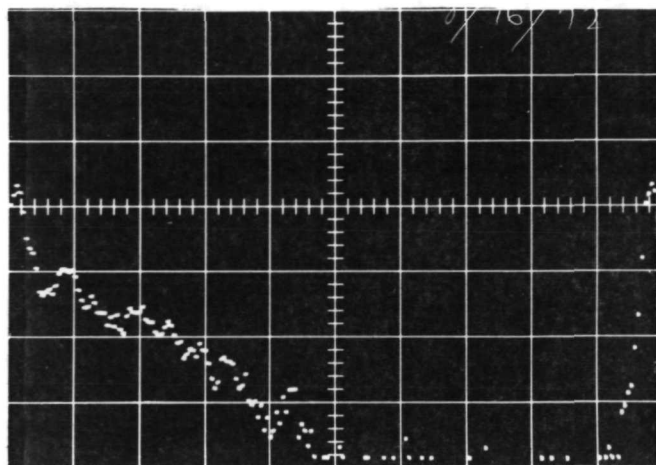


Figure 4. Spectral Analysis of Normal Pulmonary Sound

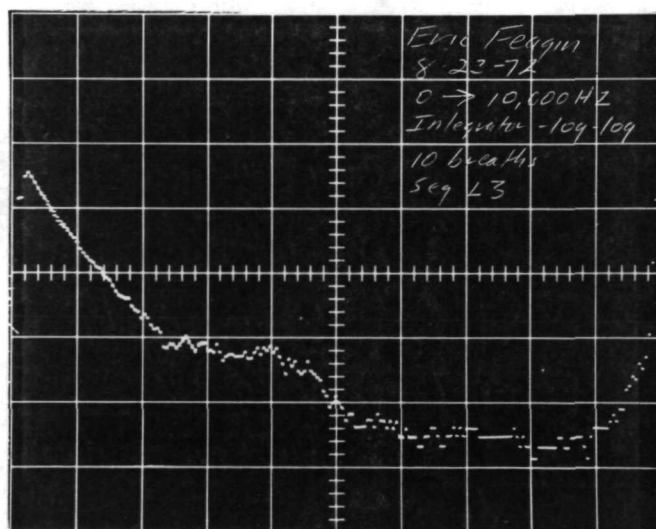


Figure 5. Spectral Analysis of Pulmonary Sounds of Patient with Cystic Fibrosis

PROBLEM MISC-27 *Improved Cushioning Material for Protective Helmets*

A material developed by NASA for spacecraft cushions has been used to reduce injury to epileptic patients when they fall.

Two teenage boys at the Western Carolina Center of the North Carolina Department of Mental Health suffer from grand mal epileptic seizures. Both these boys are normal in other respects and engage in many of the activities of normal boys, but as a result of their activity, the grand mal seizures are a constant threat of injury. Typically, if the patient is standing during a grand mal seizure, he will extend his legs, rigidize the body, and fall in some direction depending upon the particular stage of balance at the moment of the seizure. Although some patients appear to be predisposed to falling in a particular direction, all possible directions of falling are generally experienced.

When one of these patients falls, the part most likely to experience severe injury is the head. This is true because the patient generally is rigidized and falls much as a rigid body so that the head is accelerated over a significant distance. A tremendous force is generated when the head impacts whatever object lies in its path. If the patient falls upon soft earth, the possibilities of injury are not too great. On the other hand, if the patient should fall and strike a sharp, firm object with his head, the possibilities for severe injury are quite large. When one considers that these patients are completely mobile and engage in normal activities including vigorous physical exercise with the possibility of seizures as high as 20 per day, it is readily apparent that severe injury can result. Efforts have been made to provide protection to the heads of these patients at the Western Carolina Center. Through the efforts of the Western Carolina Center and the parents of the patients, the best obtainable crash helmets have been purchased and used. The helmets that seem most useful are the NASCAR racing helmets used in stock car racing. These helmets do provide protection to the patient's head within the area underneath the helmet. Even so, a severe fall frequently results in severe bruising of the patient's head when the cushioning material is completely compressed and the helmet transmits a significant portion of the shock to the patient's skull.

Because of the inadequate cushioning of the foam rubber material used in these helmets, severe bruises and lacerations have occurred in areas that should have been protected by the helmet itself. These bruises have resulted in swelling of the patient's head to the extent that the helmets could not be worn. This, of course, compounds the problem since this deprives the patient of all protection.

After examination of the helmet design and the cushioning material contained in the commercially available helmets, the Team suggested the use of the NASA-developed Temperfoam (Dynamic Systems, Route 2, Leicester, N. C.) as a potential solution to this particular problem. Information was given to the researcher on sources where the Temperfoam could be purchased. It was suggested that a laminated Temperfoam liner be employed

using a softer inner material in contact with the patient's head and a firmer grade of Temperfoam between the soft material and the fiberglass helmet structure which would absorb the impact force generated by falls. In this way it was hypothesized that maximum comfort could be obtained within the constraints of providing the necessary firmness to prevent complete compression of the Temperfoam cushioning material during impact.

Two helmets (see Figure 6) were fitted with the Temperfoam material and used by the patients (see Figure 7). Head injuries of the patients in the area protected by the helmets were drastically reduced by the use of Temperfoam. A test of 4-months duration was conducted, and comparisons were made with previous effects of the falls on the patients. The nurses were not told of the new lining material in the helmets so that unbiased reaction might be obtained. After several months use, the nurses began to note and make known to the problem originator the fact that injuries sustained in falls were significantly less severe than those that had previously been experienced. These tests clearly demonstrated the superiority of the Temperfoam material as a cushioning agent over that used in the commercially available helmets. The problem originator was very enthusiastic in his praise of the results obtained using the NASA-developed Temperfoam material. He anticipates that in all future cases at the Western Carolina Center involving such protective head gear, Temperfoam will be used.

Fortunately, modern medicine has controlled many epileptic problems so that the need for protective helmets is not widespread. Although the use of Temperfoam in protective helmets is not widely required, the use of NASA technology has directly improved the injury problem of these young men.

PROBLEM TU-29 *Damage to Blood from Microwave Heaters*

A technique developed for analysis of the blood of astronauts exposed to high oxygen pressures has been used to analyze the effect of microwave blood warmers.

Warming of refrigerated (4°C. to 6°C.) bank blood has become a common clinical practice because of the difficulties encountered with transfusing cold blood. Clinical studies have left little doubt that rapid transfusion of large quantities of blood at refrigerator temperatures may be a dangerous practice resulting in cardiac or general body hypothermia. Warming of the blood before infusion reduces the morbidity and mortality of the recipients. To avoid the effects of cardiac and general hypothermia during massive hemorrhage, cold blood should be warmed to body temperature when rapidly administered in large amounts.

Until very recently, the basic method of warming refrigerated blood involved the use of some form of water bath heat exchanger. Because human blood at 4°C. is a highly viscous fluid, coil heating systems cannot attain sufficient flow since they must force cold blood through a filter before warming. The method is relatively inexpensive, but the apparatus requires considerable warm-up time as well as some blood for priming. In addition, the precise temperature control is difficult to achieve,

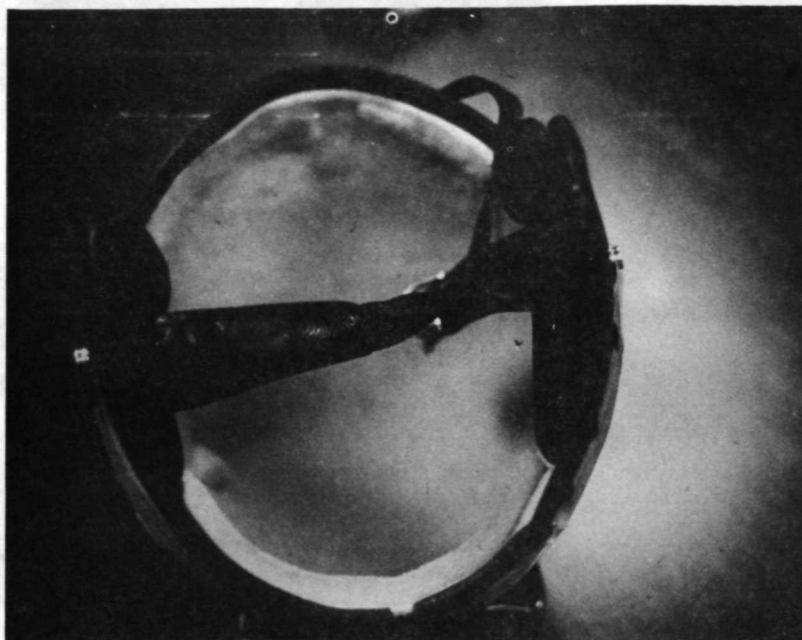


Figure 6. Helmet with Temperfoam Lining



Figure 7. Patients Wearing Helmets

and the unit must be placed close to the patient, thus adding to the equipment clutter in an already crowded operating room. Recently, the use of microwave blood warming has eliminated these problems by warming the blood in the bag before filtering, which offers speed, economy, and ease of use. The refrigerated blood can be heated to a desired temperature in 1 minute. Blood is heated only when needed so there is no wasted blood.

Microwave heating is unique in that it does not involve a hot object with the transfer of heat through conduction, radiation, or convection. Instead, electromagnetic energy is generated at a very high frequency (2.5 gigahertz) by a special oscillator tube. This sets up an alternating electromagnetic field which causes the molecules within the blood to continually try to realign themselves electrically with each field reversal. The friction between these moving molecules generates heat, thus converting electromagnetic energy into thermal energy.

Although initial tests on the use of microwave heated blood indicate that the method is basically safe, the rapidly increasing use of microwave warming demands that a more subtle test of blood damage be used to determine whether the method is safe in all circumstances. The basic problem is to find a method of determining subtle damage to blood from the microwave heating.

The potential solution to this problem was discovered as a result of a problem statement circulation in regard to problem TU-25, "Measurement of Blood Damage from Heart Lung Pumps." In response to that problem statement, Dr. Stanley Ellis of Ames Research Center suggested the use of an enzymatic technique. The technique is used at Ames for measuring the effect of high oxygen pressures in blood cells. In particular, the technique uses a proteolytic enzyme that can be monitored in a simple manner and with very high sensitivity using a specific substrate. The enzyme is dipeptidyl aminopeptidase III, which was first purified and characterized from the pituitary gland and which can be specifically determined by means of the fluorogenic substrate, arg-arg-beta-naphthylamide. [J. Biol. Chem. 242, 4623 (1967)]

The problem originator discussed the basic technique with Dr. Ellis who then agreed to process some initial samples of microwave warmed blood. Dr. Delili sent 12 units of blood to Ames Research Center for analysis using the Ames enzymatic technique. The initial tests revealed that some of the microwave warmed blood did, in fact, have a high reading using the enzymatic technique. However, not all microwave warmed blood gave the same response, which indicated that other factors were obscuring the basic phenomenon. Therefore, the problem originator sent additional samples to Ames for evaluation. These results showed a correlation with microwave damage to the blood. The problem originator plans to report the results at the 1973 Conference of the International Anesthesiology Research Society to be held at Bal Harbour, Florida.

This technique has provided new research knowledge about microwave blood warming techniques, which are commonly used in major medical centers throughout the country.

PROBLEM WF-114 *Improved Utilization of Laboratory Computers*

Techniques developed at Marshall Space Flight Center have been utilized to expand the capability of a small computer in a university medical center.

Experimental research is underway to analyze the response of animals to various drugs that affect the cardiovascular system. The experimental procedure is as follows: The animals are surgically prepared to measure a number of parameters, e.g. coronary blood flow, blood pressure, heart rate, etc., and a specified amount of a particular drug is injected into a vein of the animal. A number of different drugs are employed that are intended to either improve the performance of the heart or to attenuate the performance of the heart in the presence of atherosclerotic disease. The animals have been placed on special, atherogenic diets for up to 3 1/2 years to induce atherosclerosis. About \$1,500 to \$2,000 is invested in each animal in animal care alone.

As a result, the value of each experiment and the observations are extremely important because, after the experiment is completed, the animals must be sacrificed, and the experiments cannot be rerun. It is important to know during the actual experiment how the data being obtained compares with what has been seen in previous experiments. Since as many as 10 parameters are being monitored with 20 or 30 drug responses involving 6 or 7 drugs during a single experiment, it is just not possible to look at a current response and make the decision as to whether a given, particular trial is yielding "good" data or whether it represents an abnormal response.

In order to make a decision concerning the validity of the current data, it is desired to have available to the researcher during the experiment in real time, the updated mean and standard error of the mean for each drug and each monitored parameter from all previous experiments. Obviously, standard computing techniques can easily accomplish this using a computer. The problem lies in the real-time requirement and the fact that most research laboratories have only small computers.

Many labs do have computer terminals and access them by way of, generally, a low speed data transfer device like a teletype. Data can be transmitted to and received from a central computer in this manner. This does not, however, provide the computer data back quick enough. Most laboratories do not normally have access to high speed analog devices to permit real-time operation. In this problem the basic requirement is to update the current statistical picture of the terminal program to date; that is, the average and the standard error of the data trials, including the current data are needed in real time. The processing by which average laboratory statistics are determined is one in which each element of data is taken, a card is punched, and the deck of cards is taken to the computer center. Then one must wait for the computer to perform the statistical analysis in order to get the processed information back. This procedure is obviously too slow for the problem at hand.

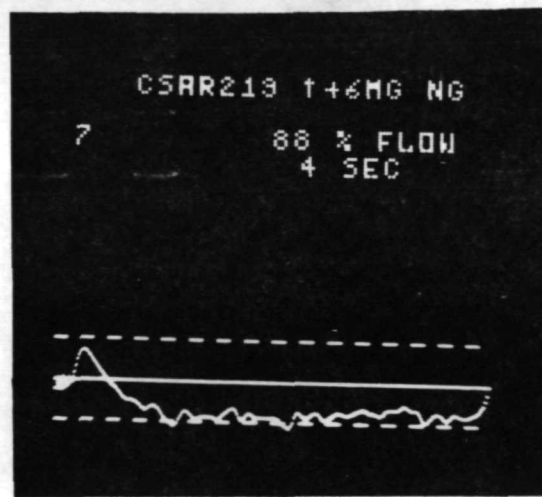
Using the LINC computer, available in the researcher's laboratory, and standard statistical analysis routines, there is just too much data. It is not possible to process the data because of the small data storage capacity of such machines. Fundamentally, the limited storage capacity (memory) of the LINC prohibit real-time statistical analysis. The LINC has only 1,000 words of data storage and 1,000 words of program storage.

If the research laboratory had a direct high speed analog line to the Computer Center at Bowman Gray School of Medicine, it would be possible to perform the computations in real time; however, from a practical standpoint, it is not practical to allow a single research laboratory to have sole and direct access to the central processing facility for 7 hours (individual experiments average this length of time). Even with the LINC, it is relatively easy to compute the average. The standard error is more complicated to obtain in terms of computation complexity. To determine the standard error, the algorithm requires access to each individual element of data. Fundamentally, the average and the standard errors of all previous trails are needed in real time during the experiment so that comparison of the current response to these data can be made. If this average and standard error data is made available during the experiment in essentially real time, it permits the researcher to determine whether the current response is acceptable.

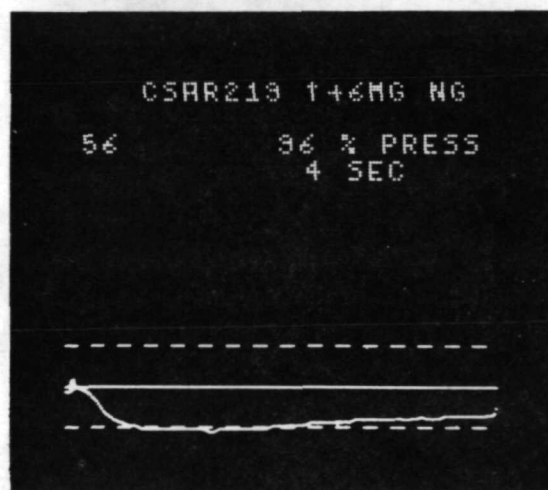
This problem was solved as a result of discussions with and suggestions from Dr. Fritz Krause of Marshall Space Flight Center. Dr. Krause has developed statistical updating routines and piecewise statistical analysis procedures that are pertinent to this problem. Basically, the techniques developed by Dr. Krause permit one to take a long duration data record and break it up into segments, sample the data, and treat this process statistically in a meaningful way. By sampling the data (rather than using the entire data record) the computer storage capacity is drastically reduced so that the computation can now be accomplished with a small laboratory computer such as the LINC. Dr. Krause has also proved the statistical validity of these techniques, which, of course, had to be done before the techniques could be used.

Use of these techniques permits the researcher to look at the mean of all the responses of all the previous experiments with other animals up to that time and compare the current response with the mean of the previous responses. This essentially gives the research a running statistical picture of all the previous data of drug responses. In the experiments six different drugs are used, so it is necessary to look at each drug and each parameter for the mean and the standard error of the mean. By comparing the current response with the mean and the standard error of the mean for all the drug responses of the particular drug up to the current response, it is possible to decide whether the data being currently obtained is good data or abnormal data. The standard error of the mean is very useful in making this decision meaningfully.

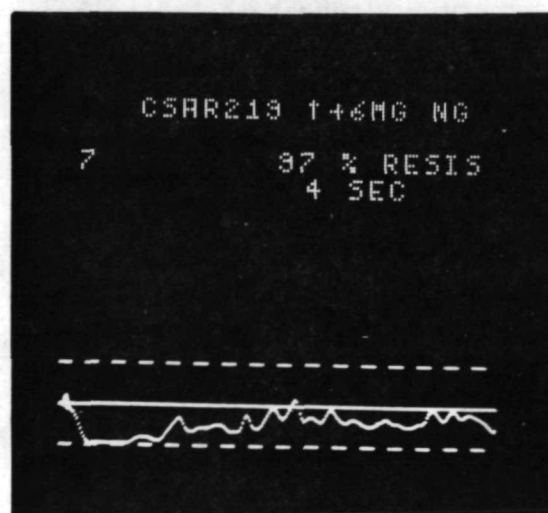
If the data is considered good data, then the current response is included, the data is update, and a new mean and standard error of the mean are obtained very rapidly and with very little programming effort.



(A) Flow



(B) Pressure



(C) Resistance

Figure 8. Example of Cardiovascular Data Calculated Using Piecewise Statistical Analysis

If the response is abnormal (different), then there are a number of things associated with the experimental technique that could cause abnormal response data; there may be bubbles in the transducer systems, the animal may not be anesthetized properly, the drug may not have been administered properly, etc. Since the implementation of this transfer, it is now possible to detect when a response is abnormal and then check the entire experimental setup and make the necessary corrections. Then the drug is given again to obtain good data.

Consequently, by having the mean and standard error of the mean available, the researcher is able to detect abnormal data, while the animal is still alive, and make the necessary corrections to obtain good data. It makes the difference between obtaining reliable data and discovering, after the animal has been sacrificed, that the experiment did not yield any useful information. It gives the researcher the opportunity to take a second look at something that may be questionable, and improves consistency and reliability in the experimental technique as well.

If the data for a single experiment were updated by hand, it would take someone 2 weeks to do it. Using the techniques developed by Dr. Krause, the existing LINC computer can accomplish the same thing in about 20 seconds. The period of time is very important because with only a 20-second wait the researcher is now able to make the comparison with other data while the animal is still alive. But more importantly, if the data is abnormal the experiment can be run again while the animal is still alive to determine where the cause of the abnormal data lies, and thus provide the opportunity to obtain good data which would otherwise be relegated to the scrap heap as a bad experiment. This is of some significance when one considers the time involved in preparing and conducting the experiment plus the animal cost of several thousand dollars. An example of experimental use of this technique is shown in Figure 8.

This technique has applicability in any laboratory where data analysis is limited by computer memory. Although the technique was installed on a computer that is not widely used, it can be easily implemented by a computer programmer who has knowledge of the algorithm. This will become widely available when the problem originator publishes a paper, now in preparation, that describes the technique. The use of this technique will significantly enhance the capability of medical researchers to analyze slowly varying biological signals that have a poor signal-to-noise ratio.

2.2 Potential Technology Applications

During the reporting period, three problems achieved the status of potential technology applications. This status indicates that an adequate solution to the problem has been identified and implementation is in various stages of accomplishment. These three problems are discussed in the following summaries.

PROBLEM NCI-13 *Portable Isolation Garment*

A garment designed to isolate Apollo astronauts upon return to earth has been used to provide a portable sterile environment for cancer patients undergoing chemotherapy.

The National Cancer Institute (NCI) has pioneered the use of laminar flow rooms to provide sterile environments for patients undergoing chemotherapy. This is required because the various drugs used in the treatment of diseases such as leukemia cause a severe reduction in the number of white cells, and thus, the patient has a high risk of contracting an infectious disease. The second benefit, which is as yet unexplained, results from the fact that the patient is able to tolerate higher drug doses in the sterile environment than in the normal environment. For the past several years the National Cancer Institute has treated adults in these laminar flow rooms with great success and, recently, they have started using the rooms in the treatment of children. In comparison with adults, children are less able to psychologically tolerate confinement to one room, so it is desirable to be able to remove the patients from the laminar flow rooms for brief periods while still maintaining a sterile environment. In addition, it is important to permit the patient to be transported to another part of the hospital for a medical procedure such as diagnostic X-ray or therapeutic radiation. Unfortunately, no such portable isolation chamber existed for these patients. The basic problem is to provide a sterile environment by filtering the air (remove particles greater than 0.3 micron) in order to reduce the possibility of infection from a variety of airborne particles.

Mr. William Z. Penland of the National Cancer Institute contacted Dr. F. T. Wooten of the RTI Biomedical Application Team in October 1972 to ask for assistance in solving the problem of providing a portable isolation chamber for patients outside of the laminar flow room. It would be desirable to be able to remove these patients for periods up to 4 hours. Dr. Wooten identified the NASA Biological Isolation Garment (BIG) (see Figure 9) as a possible solution to this problem and contacted Mr. John T. Wheeler, Technology Utilization Officer at the Manned Spacecraft Center (MSC), who quickly identified Mr. Fred Spross as the cognizant technical staff member at MSC. Following technical discussion of the problem with Mr. Spross, Mr. J. C. Stonesifer of MSC forwarded a NASA BIG to NCI for their evaluation. The NCI staff used the BIG with normal individuals in order to determine its relevance to the particular problem. The quick loan of this garment to NCI stimulated their interest in this particular problem and expanded the basic idea to provide for its use in a wider range of applications.

The NASA Biological Isolation Garment is described in NASA patent #3,516,404, which is listed in the NASA document file as N71-17599. The NASA BIG was designed for the Apollo astronauts to wear upon return to earth in the splashdown phase. The unit was designed to be specifically worn from the time of egress from the command module to the time of arrival in the portable quarantine facility on board the recovery carrier. The



Figure 9. Apollo 11 Astronauts Wearing Biological Isolation Garment

NASA garment was designed to prevent contamination of the earth environment in the event that the astronauts were carrying some micro-organism. Thus, the NASA unit was designed for the inverse problem of the National Cancer Institute problem. The NASA unit was designed to prevent contamination of the earth's environment by the astronaut whereas the NCI application is designed to prevent contamination of the patient by the earth's environment.

The major problem with the existing BIG concerns discomfort caused by heat and the claustrophobic aspect of the face mask. The NASA garment was designed for use with healthy adult males who are able to better tolerate a face mask than a seriously ill patient. The existing face mask also accounts for part of the total weight of the garment and it would be desirable to reduce the weight if possible. Thus the NCI personnel decided to add a positive pressure portable air supply, which will offer advantages not only in the area of heat and weight reduction but also from the standpoint of contamination control. For example, many of the contaminants come from the surface of the patient's body; providing a directed flow of air from the top of the head downward would reduce the danger of self-contamination. The reduction in sealing requirements might also reduce the need for pressure sealing zippers, which are more difficult to operate than a simple Velcro fastener.

The NCI research team asked one of its contractors, Arthur D. Little, INC., to design a garment based on the NASA design but modifying the face mask to better suit the needs of the NCI patients. The contractor has performed extensive analysis of the flow in the existing BIG and has been able to incorporate the relevant features of the NASA garment into the NCI garment. A prototype of the NCI garment has been built and delivered to NCI for clinical evaluation.

When this technology application is complete, it will be an excellent example of how technology utilization should work. It is apparent that in less than 1 month, it was possible to deliver to the NCI research team a garment that incorporated many of the desirable features needed for this problem. Utilizing the experience gained in the development of the NASA garment, the NCI research team was able to go immediately to a prototype design which will save significant time in bringing a needed technological development into clinical practice.

This garment is expected to have use wherever the laminar flow concept rooms are used in chemotherapy. These rooms are used extensively now by the National Cancer Institute, and several hospitals are building facilities for their use.

PROBLEM TU-33 *Silica Measurement in Microgram Quantities*

A technique used by a NASA research team for analysis of small dust samples has potential for analyzing small quantities of silica dust collected in research on silicosis.

Silicosis is a disease of the lungs caused by inhalation of dust containing free crystalline silica over a prolonged period varying from 5 to 25 years.

Industrial procedures that result in dispersion of free silica into the air include the mining of lead, hard coal, copper, silver, and gold; sandstone and granite cutting; metallurgical processes using free silica; and the manufacture of silica abrasives. Only dust containing small particles of free crystalline silica (less than 10 micrometers in diameter) can cause silicosis. The allowable maximum concentrations in industrial dust are stated to be around 25 million particles per cubic foot of air if the free silica content of the dust is less than 10 percent but down to 2.5 million particles per cubic foot if the silica content is greater than 50 percent.

When free silica particles are taken into the small pulmonary passages, a local fibroblastic proliferation occurs with a resulting decrease in maximum breathing capacity. As silicosis progresses, pulmonary function is gradually decreased by reducing the vital capacity of the lungs.

Although silicosis has been studied for many years, a new form of the disease has recently appeared. This disease, called accelerated silicosis, can result in death after 3 years of exposure as compared with the more typical 25-year period for miners. Accelerated silicosis has been found to occur frequently among workers engaged in sandblasting, e.g., as commonly used on the drilling platforms in the Gulf of Mexico. Staff members at the Tulane School of Medicine have noted a rise in the occurrence of accelerated silicosis with the increase in number of drilling platforms off the coast of Louisiana. A study is now underway to characterize the environment of the workers who are susceptible to this disease. A method exists for the sampling of the air around the workers that produces only microgram quantities of the dust. A method for analysis of the silica content of these small samples is necessary, in order to carefully characterize the environment of the workers.

Between 30 and 300 micrograms of the dust is contained on a 50-milligram filter. The filter is a 0.8-micrometer Millipore type, and an analysis procedure with a precision of ± 5 percent is desired.

The problem originator investigated wet chemistry and X-ray diffraction methods but found these to be unsuited for the very small sample sizes obtained from the workers.

Mr. John Samos, Technology Utilization Officer at the Langley Research Center (LRC), noted this problem in one of the team's monthly reports. As a result, Mr. Samos identified Dr. Roger Jolly of LRC as an individual knowledgeable in this area. Dr. Jolly suggested the use of X-ray fluorescence techniques that have been used at the Langley Research Center.

Following a conversation between Dr. Jolly and Dr. Ziskind, it became apparent that the proposed method had a high probability of solving this problem. Dr. Jolly has volunteered to analyze some of Dr. Ziskind's samples and, in addition, Dr. Ziskind plans to visit Dr. Jolly to learn more of the details of the technique.

If successful, this research tool will provide additional insight into the cause of a crippling or fatal disease.

PROBLEM VAM-13 *Corrosion and Fracture of Orthopedic Implants*

An aerospace research team has provided new insight into the cause of failure of widely used orthopedic implants.

Metals and alloys are currently used in a number of bioassistants such as pace-makers and heart valves. The most widespread use of metallic implants is found in a multitude of orthopedic devices. One of the most common examples of an orthopedic implant is the fracture brace, which consists of a stainless steel plate and stainless steel screws for attaching the plate to the bone. The plate serves to hold the bone in place while the fracture mends as well as to give added support to the fractured region. In healthy persons, the implant will usually be removed after the fracture has healed. In many instances, however, the plate will fracture prior to the healing of the bone. When an implant fails in service, it must be removed immediately. In the aged or in persons having a poor state of health, the trauma of a second operation to replace the fractured implant may severely hamper the patient's ability to recover.

A recent study indicates that the incidence of fracture is on the order of 9 percent. There have been few comprehensive investigations of the causes of failure of metallic orthopedic implants where both patient history and metallurgical examinations can be combined to conduct a complete analysis of the initialization of the failure mechanism. The problem originator had obtained fractured implants from several clinical institutions in Florida and wished to obtain competent assistance in determining the causes of failure. A better understanding of the causes of failure should lead to improved metallurgical and manufacturing procedures and perhaps to improved surgical procedures for implanting orthopedic devices.

Mr. John Samos, Technology Utilization Officer at LRC, referred the Team to two engineers, Dr. Bland Stein and Mr. Barry Lisagor, who were interested in studying the problem. The problem originator visited Langley to discuss the problem in detail and brought with him samples of failed orthopedic implants. Two of the implants had failed soon after implantation; one had failed within 1 week and the other within 5 weeks. These samples offered a unique opportunity to study the nature and mechanism of early failure. Although such early failures are not uncommon, a study of implants that failed soon after implantation has not been located in the literature.

Dr. Stein and Mr. Lisagor studied the samples using a Langley electron microscope (see Figure 10). The underlying cause of fracture in the two samples appears to have been stress corrosion. It is not yet clear whether the residual stress in the material was due to the manufacturing process or to the surgical procedure of attaching the implant to the bone. The body's environment served as a catalyst to hasten the fracturing process. Electron microprobe analysis has been carried out to determine whether the implant material is within A.S.T.M. specifications for 316L stainless steel; however, this study is not yet complete.

It is anticipated that this study will provide new insights into the cause of failure of widely used implants such as hip pins. This may allow corrective action to be taken that will eliminate the common failures.



Figure 10. Electron Micrograph of Hip Pin Fracture

2.3 Impacts

The Application Team's efforts often provide a significant benefit to the researcher even though no technology application has been accomplished. During this reporting period, Team activities had a significant impact on the researcher's activities in one such problem that is discussed in the following summary.

PROBLEM MISC-29 *Nurse-Call for Quadriplegic*

There are many persons for whom conventional push-button nurse-call switches are useless. Among those who cannot use conventional nurse-call switches are patients who cannot exercise voluntary control over arm or hand muscles (e.g., quadriplegics, multiple sclerosis patients, etc.) as well as patients incapacitated by burns on upper extremities. Many of these patients depend upon the services of nurses for practically all of their needs. Improved nursing care could be provided by the installation of a nurse-call switch that could be actuated by the patient. The patients requiring such a signalling system generally have voluntary control over one or all of the following functions that could conceivably be used to actuate the switch:

- (1) breath;
- (2) eye movement and blink; and
- (3) head motion.

Generally, complicated systems that require frequent adjustments or maintenance are undesirable because of the lack of skilled technicians in most hospitals.

This particular problem originated at the Conway Nursing Center in Conway, S. C., where there is a quadriplegic who has no voluntary control over his limb muscles.

The breath-actuated switch conceived at NASA's Langley Research Center and originally implemented by the Southwest Research Institute BATEam provides a novel solution to this problem. The heart of this system, commonly called the puff-switch, is a microswitch that can be actuated by as little as one-half ounce of force. The force produced by the patient's blowing upon a small diaphragm attached to the switch is sufficient to close it. The switch is easily actuated at distances up to 1 foot.

The puff-switch implemented by the RTI Team differs from previous puff-switches in that all movable parts are enclosed in a protective housing to make the unit

more durable in the hospital environment. The puff-switch was compatible with the commercially available nurse-call system in use at the Conway Nursing Center which permits communication between the nurse station and the patient by means of an intercom system; the push-button switch normally used by the patient was simply replaced by the puff-switch. The unit is currently in operation. (See Figure 11)

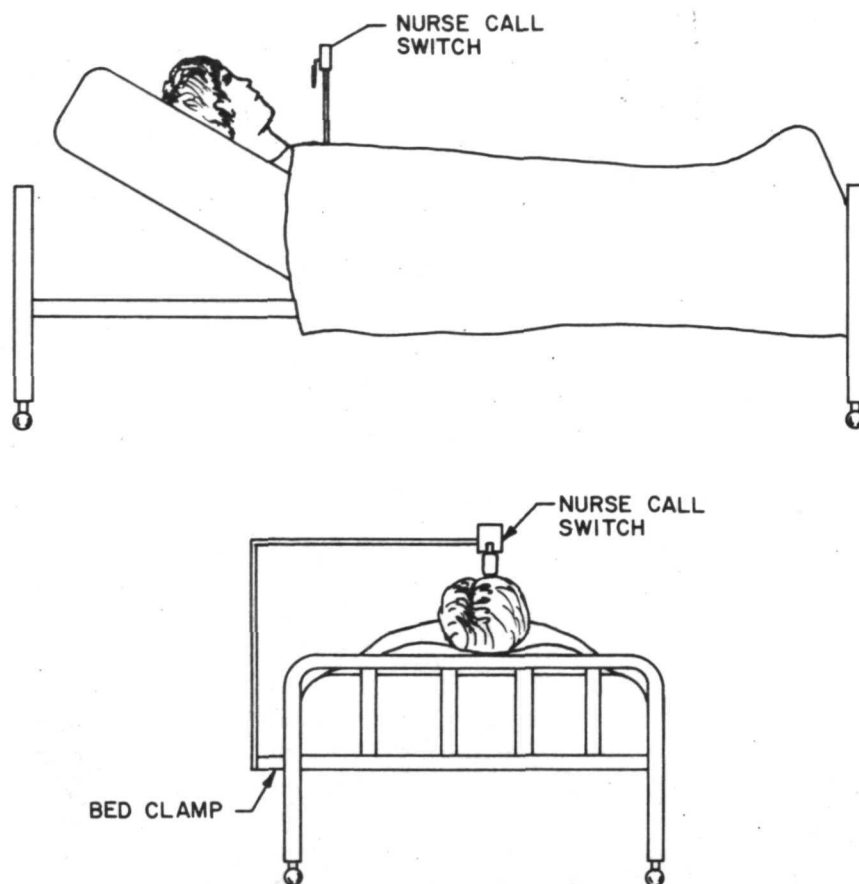


Figure 11. Nurse-Call Switch For Quadriplegic.

3.0 SUMMARY OF TEAM ACTIVITY DURING REPORTING PERIOD

3.1 Problem Activity Summary

The following is a summary of project activity undertaken by the RTI Team during the period September 1, 1972, to February 28, 1973.

<i>New Problems Accepted</i>	21
<i>Problems Rejected</i>	2
<i>Problems Inactivated</i>	21
<i>Problems Reactivated</i>	0
<i>Total Problems Currently Active</i>	57
<i>Preliminary Problem Statements Prepared</i>	21
<i>Problem Statements Disseminated</i>	2
<i>Responses to Problem Statements</i>	7
<i>RDC Computer Searches Initiated</i>	7
<i>Impacts</i>	1
<i>Potential Technology Applications</i>	3
<i>Technology Applications</i>	4

A description of currently active problems categorized by health area is attached as Appendix B.

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4.0 APPLICATIONS ENGINEERING PROGRAM

Selected problems have been accepted for implementation of technology under the Applications Engineering Program. In the program, the technology is actually implemented by NASA. Activities for these eleven problems are presented in the following summaries.

PROBLEM DU-31 *Catheter-Mounted Pressure Transducer*

A pressure transducer developed for use in the aerospace program has been modified for measurement of pressure in human hearts.

Heart disease is the major cause of death among the American people. The disease affects every age group, and it is extremely interesting that the youngest age group, infants, demonstrates nearly all varieties of abnormal cardiac condition. Thus, the study of pediatric heart disease is of major importance. Many types of abnormal heart conditions in children can be surgically corrected, but proper diagnosis becomes of paramount importance. The correct diagnosis of heart disease in children requires very careful measurements of pressure and volume of the heart. The arteries and heart chambers are very small and require an unusually small catheter for making various measurements. One of the measurements of great importance is pressure in the aorta and in all four chambers of the heart. This pressure measurement is more difficult in small children because heart rates can range as high as 300 beats per minute. Thus, the pressure transducers must be able to measure rapid changes in pressure and very small gradients in pressure in order to detect the abnormalities in heart condition.

A major research effort at Duke University Medical Center is devoted to understanding the heart diseases in children. In particular, the research is devoted to determining a correlation between pressure changes in all four chambers of the heart with motions of the chest wall. The motions of the chest wall can be detected by an apex cardiogram. Thus, a correlation will be made between a measurement technique requiring penetration of the heart and a measurement technique entirely external to the body. It is necessary to measure pressure, but the existing methods of measuring pressure do not have sufficient sensitivity, frequency response, or size capability. Also, fluid-filled catheters, which are commonly used, cause significant over-shoot in the contraction pressure waveform. Thus, a new pressure-measuring device is required.

A pressure transducer with size #5 French (1.5 mm) or smaller is required. The pressure range is -30 mm to +300 mm Hg. The maximum frequency of response is undetermined but frequencies as high as 100 Hz may be encountered. Pressure resolution of 1 mm Hg is required, and temperature compensation from 35°-40°C is required. The transducer should be mounted on the side of a catheter to prevent erroneous readings due to motion of the catheter against the heart wall.

The solution to this problem appears to be the tunnel diode transducer developed by Dr. W. Rindner at Electronics Research Center. Dr. Rindner has formed his own company, Device Research, Incorporated, and is presently offering the NASA-developed transducer. The Duke researcher has examined the specifications of the Rindner TD-1 Transducer and believes that this will solve his problem.

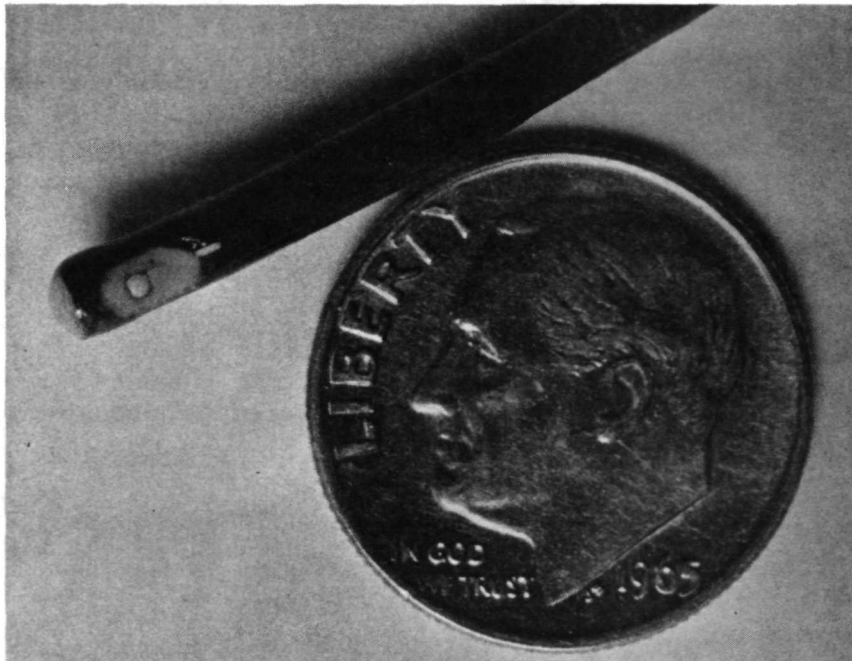


Figure 12. Tunnel Diode Pressure Transducer

The TD-1 pressure transducer, shown in Figure 12 is presently undergoing tests at Duke University Medical Center to determine its characteristics in animal experiments. Initial tests indicated excellent sensitivity but some problems in thermal drift. Dr. Rindner is modifying the transducer to solve this problem.

PROBLEM DU-48 *Urine Flowmeter*

Diseases of the urinary system are significant medical problems. One of the problem areas concerns the ureters, i.e., the tubes that connect each kidney to the bladder. Urine-flow measurements in the ureter are being used in a research study to gain knowledge of ureteral physiology. Improved flow-measurement techniques also could be used in clinical studies of kidney, ureteral, and bladder diseases. All existing techniques for measuring flow in the ureter involve collecting samples of urine over definite intervals of time and calculating average flow rates. These average flow measurements are not satisfactory when the pulsatile nature of flow in the ureter is being studied. This pulsatile flow of urine is felt to be a very important factor in obtaining a better understanding of ureteral physiology.

The requirement here is for a technique that employs a transducer for measuring instantaneous rates of urine flow in the ureter. The transducer can be used either internally or externally. If an external transducer is used, the flow of urine can be diverted to a point outside the body using a catheter.

The flowmeter should measure transient urine flows of from 1 to 100 cc/min with an accuracy of \pm percent. Size of the flowmeter is not important because it can be outside the body. A flowmeter using the principle of thermal distribution developed for the Skylab flight program appears to be a potential solution to this problem but modifications in the Skylab device will be required. The NASA contractor building the Skylab device has agreed to build the modified device and an application engineering request has been submitted to NASA Headquarters.

PROBLEM DU-74 *Testing of Neuropathic Patients*

A system designed to measure pilot performance will be adapted for the study of neuromuscular disorders.

Many people suffer neuromuscular disorders that result in the loss or impairment of muscular control. The cause of these disorders is damage to the nervous system that controls the musculature. One symptom of this disorder is uncontrollable contraction and relaxation of muscles.

Modern therapeutic treatment allows many thousands of patients to improve the degree to which they can exercise voluntary control over their muscles and, therefore, to assume a more active and useful role in society. Therapeutic treatment, however, is presently hampered by the difficulty of measuring the improvement that individual patients make during the course of therapy. As an example of a currently employed technique for measuring a patient's progress, the patient is presented with a drawing of a thin-lined geometrical pattern and is asked to trace the pattern with a pencil. From this experiment, one can make a subjective judgment regarding the degree to which a patient is able to control the movement of his hand. A more quantitative measurement of a patient's progress would lead to refined therapeutic techniques, which, in turn, should bring about more rapid and more complete recovery for the many patients suffering from neuromuscular disorders.

In the design of highly reliable aircraft and space systems that are to be operated under direct manual control, the problem of the man-machine interface becomes critical. Scientists at NASA's Langley Research Center have been working for several years on the problems of designing flight vehicles that are well suited for control by a human operator. Of major importance is the understanding of the motor and perceptual characteristics of the human pilot. To measure pilot characteristics such as limb controllability, response time, rate of movement, etc., LRC researchers developed a variety of tests and testing apparatuses. This research resulted in a mathematical model of the human pilot.

The Team learned of this research at Langley and arranged a visit to talk with two of the pioneers in pilot modeling. Upon discussing this problem with the Langley researchers, it became evident that the tests they had devised to determine pilot characteristics had much in common with the requirements for testing patients with motor disorders. The Team was given a demonstration of a tracking task that was employed at LRC. In this case, aircraft pilots were required to track an oscilloscope trace of a noisy signal using a joystick manipulator. With this configuration, it was possible to record both pilot response and instantaneous error in tracking random disturbance. Included in the LRC tasks were control stick and aircraft dynamics. This configuration is illustrated in Figure 13 for a single-axis tracking task. The Langley researchers suggested that the stick and aircraft dynamics be removed from the tasks in order to acquire a better measurement of the motor performance of neuropathic patients. The LRC tracking unit with the suggested modifications as shown in Figure 14 has been evaluated by the problem originator.

The LRC system will provide much quantitative information on human motor performance; however, a modified version of the manipulator will be required to make the test results less sensitive to the patient's perceptual performance. Engineers at LRC have agreed to give assistance in the design of a unit for administering and analyzing the results of tracking tasks. This system is expected to be employed in a clinical environment at Duke.

PROBLEM NCI-3 *Automatic Blood Pressure Measurement of Critically Ill Patients*

Equipment designed to monitor astronauts during ground training is being used in the monitoring of leukemia patients. Leukemia, a major form of cancer, is a disease characterized by a self-penetrating proliferation of white blood cell forming tissue.

The National Cancer Institute (NCI) is conducting a vigorous program directed toward finding the causes and cure for this disease. In the clinical phase of this program, a problem exists in the early detection of shock, which is defined as a sudden reduction in the volume of circulating blood. Shock often occurs as the result of hemorrhage, infection, or a combination of the two; but if not recognized early, shock becomes irreversible and rapidly fatal.

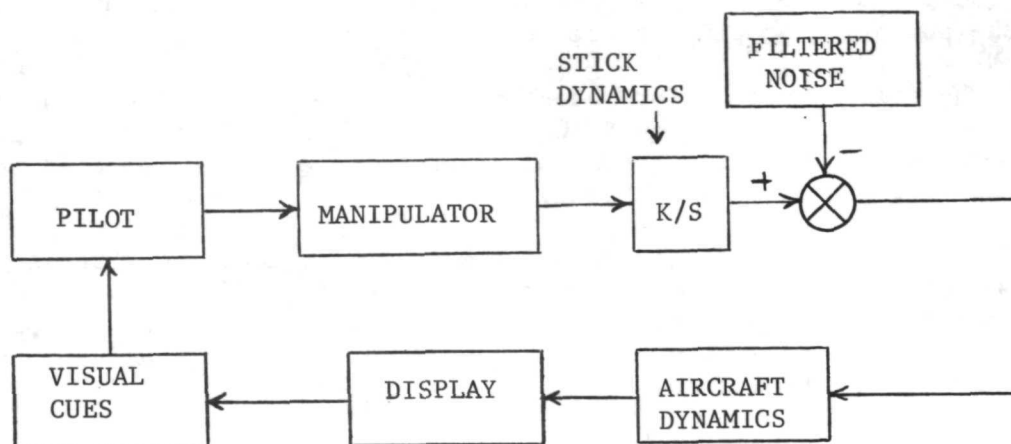


Figure 13. Single Axis LRC Tracking Task Block Diagram.

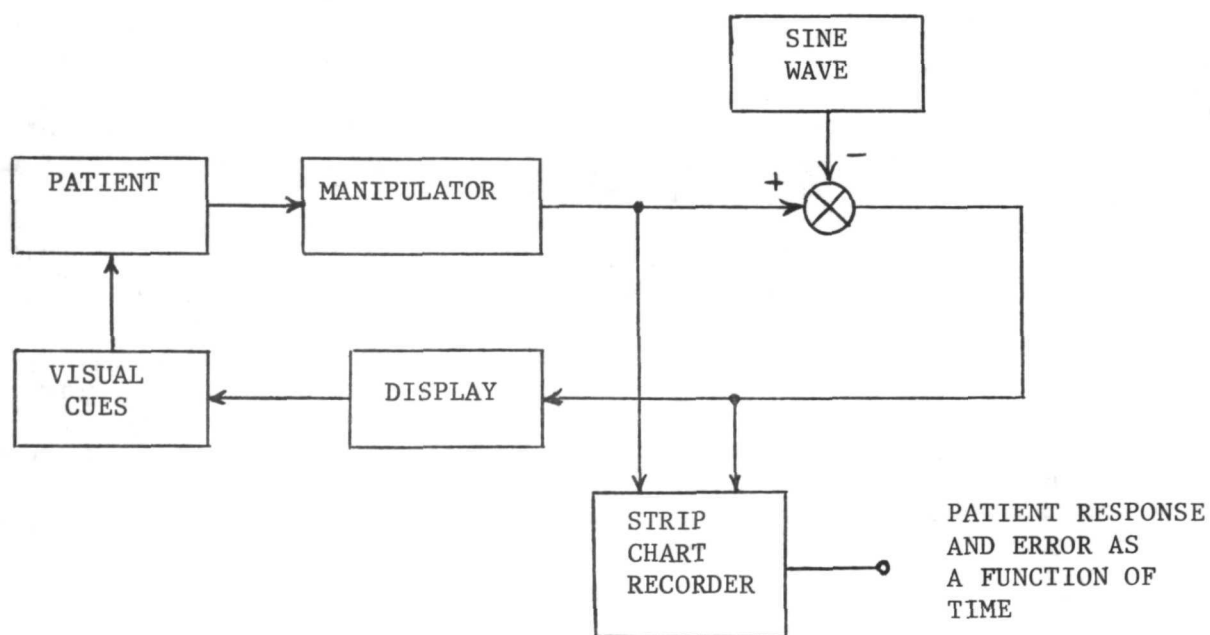


Figure 14. Block Diagram of Single Axis Track Task for Testing Neuropathic Patients.

Thus, a need exists for an accurate indicator of the onset of shock so that corrective measures can be taken.

One important measure of the onset of shock is a reduction in blood pressure. Blood pressure is defined as the pressure exerted by the blood within the arteries. The two pressures of interest, systolic and diastolic, are the maximum and minimum pressures exerted on the walls of the arteries by the pulsatile pumping of the heart.

The primary method for measuring blood pressure is the sphygmomanometer, which is a cuff placed around the upper arm. The cuff method is undesirable for continuous monitoring of blood pressure because the repeated inflation of the cuff disturbs the patient.

A method for monitoring blood pressure on a continuous basis is needed for bed patients. The method should not significantly disturb the patient. The pressure range of interest is 0-200 mm Hg and a sensitivity of 5-10 mm Hg is required. An invasive technique (i.e., one that punctures the skin) is considered undesirable.

A computer search of the NASA document file was made as the first step toward finding a solution to this problem. Although the search revealed a number of interesting documents, no adequate solution was found. However, the search revealed that Ames Research Center had conducted much of NASA's research in blood pressure measurement. During a trip to Ames Research Center, the Team discussed the problem with Mr. Joseph R. Smith who suggested that an alternate approach would be to use the oximeter developed by ARC for measuring blood oxygen content. This device was designed to clip into the upper part of the ear and measure the oxygen content of the peripheral blood during various ground testing operations such as centrifuging. This approach was discussed with the problem originator, and it was agreed that the approach was a useful one.

The oximeter, shown in Figure 15, operates by measuring the infrared absorption through the upper part of the ear by placing an infrared source and a detector on opposite sides of the ear.

The output of the meter is a measure of the oxygen in the blood of the ear. Since the constantly changing blood volume of the ear is caused by the blood pressure changes, the output of the oximeter is affected by changes in the blood pressure. Thus, the unit can be used to obtain a relative measure of blood pressure but not an absolute measure. The problem originator stated that the relative change in blood pressure was of major interest because it is this relative measure that is of importance in detecting the onset of shock. The problem originator also stated that tests needed to be conducted to determine whether the peripheral blood pressure could be used as an adequate measure of the onset of shock.

Initial tests on the device indicates drift problems due to the age of the instrument. An applications engineering request has been submitted to NASA Headquarters to build a new model of this device.



Figure 15. NASA Ear Oximeter.

PROBLEM NCI-4 *Controlled Rate of Freezing a Liquid*

Leukemia, a disease that kills about 15,000 Americans annually, is characterized by a proliferation of the tissue that forms white blood cells. Although the white cells in the blood can either increase, decrease, or remain constant in number, the bone marrow where the cells are formed will proliferate.

Treatment of leukemia involves killing the cancerous white blood cells in the blood and in the bone marrow using drugs or radiation. This process can cause loss of all bone marrow so that normal white cell production cannot occur.

When this loss of bone marrow occurs, white cells must be resupplied to the patient. For this purpose a bank or storage facility of white cells is required. This is impossible at present because adequate storage procedures are unavailable. Although red cells can be preserved by freezing, white cells are now destroyed by the existing freezing and thawing procedures. One important parameter in freezing white blood cells is believed to be the rate of freezing. Rate of freezing cannot at present be controlled because of the plateau in cooling rate when the latent heat is released at the freezing point.

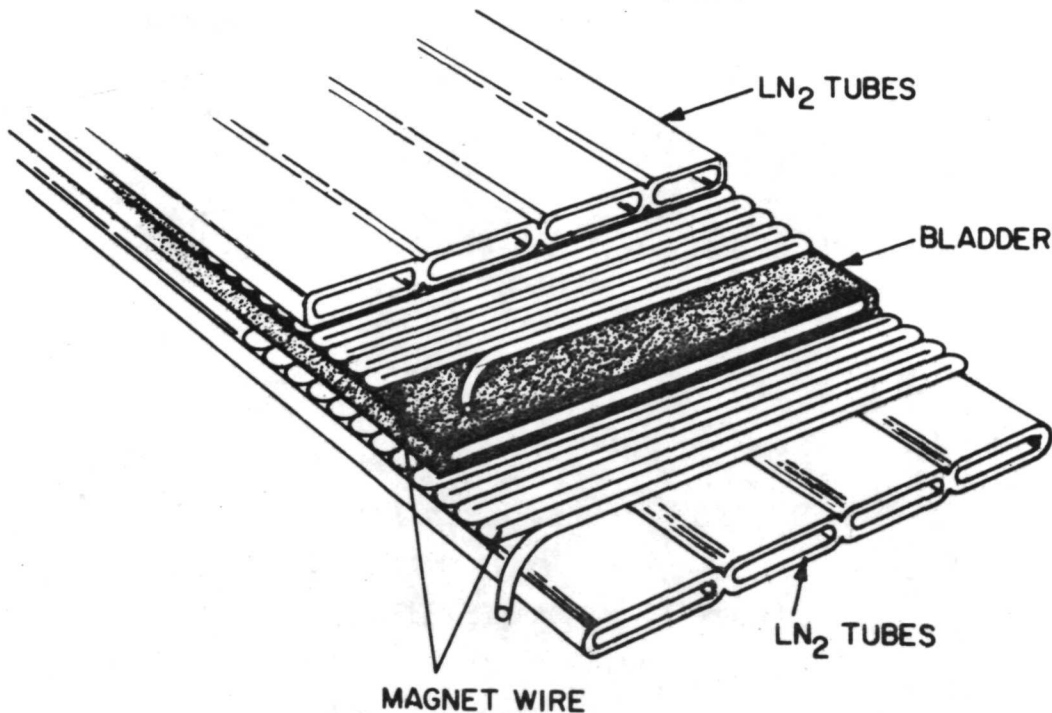


Figure 16. Controlled Freezing Unit.

The present method for freezing is a liquid nitrogen system, which cools a secondary liquid, which in turn cools the cells contained in a flat Teflon bag. To prevent contamination of the cells, it is desirable that any new technique utilize a Teflon container.

The basic requirement is to have a method of detecting the onset of freezing and then increasing the heat transfer rate during the release of latent heat so that a nearly constant rate of freezing can be maintained from room temperature to -50°C .

This problem was forwarded to the Jet Propulsion Laboratory (JPL) where Mr. L. S. Doubt and Mr. W. Tener suggested the configuration shown in Figure 16. The cells are held in a Teflon bladder, which is surrounded by a copper heating element and liquid nitrogen tubes. During the cooling cycle from room temperature to the freezing point, the heating coils control the cooling rate. At the freezing point, the heat is turned off and the latent heat of the cells is rapidly removed. Then the heat is turned on again to control the rate until -50°C is reached.

Although the proposed solution originated at JPL, implementation of this idea is being pursued by the Goddard Space Flight Center (GSFC) because of the geographic proximity of NCI and GSFC. GSFC personnel are now using computer aided design to optimize the basic configuration before hardware construction begins. The computer analysis utilizes the same techniques that NASA uses in space applications such as thermal balance in spacecraft. Coordination between NCI and GSFC research staff members will be closely maintained to insure that the final device will meet all medical and engineering requirements.

Initial studies showed that a minor modification of the initial concept was required. A computer simulation model was developed that allowed design modifications to be quickly evaluated. Following this phase, an experimental model of the design was built and tests are underway. It is anticipated that an experimental model will be delivered to NCI during the spring of 1973.

PROBLEM OF-2 *Bone Density Measurement*

A technique developed for measuring calcium loss in astronaut bones may prove useful in measuring calcium loss of cancer patients.

One of the many effects of a cancer is the secretion of a hormone that leaches calcium from the bone. This can produce lethal hypercalcemia. For example, 20 percent of lung cancer victims and 40 percent of breast cancer victims have hypercalcemia during the course of their diseases. Although some forms of hypercalcemia can be treated medically, the fundamental cause of its occurrence is unknown. In studies of experimental, tumor-bearing animals that secrete a hypercalcemia-producing substance, measurements of bone density would be useful in order to follow the progress of demineralization. Thus, a method of measuring bone density in experimental animals to be used in basic research on cancer is required.

At present, bone density is measured using the radiographic method in which an X-ray is made of the bone and the density of the X-ray film is

used as a measure of the bone density. This method is unsuitable for repeated measurements because of the high doses of X-rays required. For complete safety, dose levels should not exceed 5 rads per year for continual exposure. A method that does not involve X-rays would be desirable.

Although the technique will be used eventually on human beings, initially it will be used on rat tibia (3 x 0.5 cm). Changes in bone density as high as 50 percent are expected and the accuracy of detection should be ± 5 percent. Preferably, the rat will not be sacrificed so that repeated measurements can be made over a 14-week period. Large numbers of animals bearing tumors can be utilized, allowing for destructive measurement comparisons to be made.

A technique developed to measure astronaut bone density on the Skylab flights has been identified as applicable to this problem. Basically, this device (shown in Figure 17) measures the ultrasonic velocity through the bone, which could be correlated with bone density.

Discussions with Dr. Ray Gause and Mr. Jim Hoop of MSFC revealed that this instrument was directly applicable to this particular problem. A complete description of the instrument was given to the problem originator, who has stated that he would like to obtain such a unit for his experimental studies. Plans are now being made to lend the MSFC bone densitometer to the Ochsner research group. Initial tests on the densitometer at the Baptist Hospital in Memphis have indicated that the device will be an excellent solution to this problem. Mr. Jim Hoop has designed and built a modification of the transducer in order to fit the experimental animals.

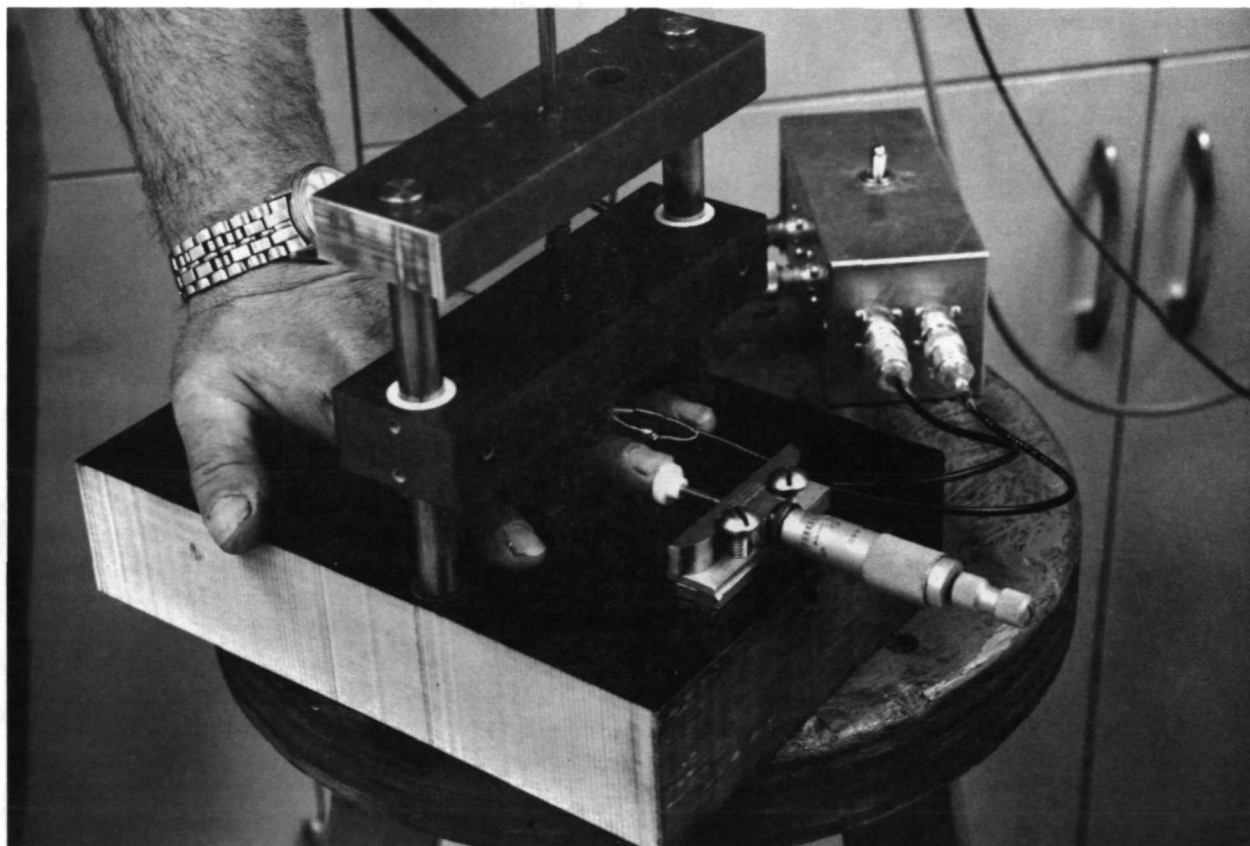


Figure 17. NASA Bone Densitometer.

PROBLEM VAM-6 *Negative Pressure Chamber*

Respiratory distress syndrome (also called hyaline membrane disease) is the major cause of death in the newborn. It is estimated that more than 20,000 babies succumb to this disease in the United States each year. Respiratory distress syndrome is a condition of the newborn in which the lungs are collapsed; it is thought to be due to the absence, because of immaturity, of an alveolar substance that decreases the surface tension and permits lungs reexpansion after each expiration.

Recently, researchers at several medical centers in the United States and Canada have produced encouraging results with the use of continuous positive airway pressure (CPAP) and continuous negative pressure (CNP) therapeutic techniques. The CPAP method makes use of an endotracheal tube which continuously forces oxygen-rich air into the lungs while the CNP method keeps the infant's lungs expanded by subjecting the chest to continuous negative pressure. The negative pressure around the chest helps the infant to expand his lungs and to maintain the proper residual volume of air. If life can be sustained for 4 days by either method of treatment, the missing surfactant will become present in a sufficient quantity for normal breathing to occur.

The CNP method has been employed by specialists at the University of Miami School of Medicine who were among the first to make use of the technique. A commercially available respiratory was modified to produce a constant negative pressure and has proven successful in saving the lives of several infants. The University of Miami researchers, Dr. Akram Tamer and Dr. Eduardo Bancalari, recognized several shortcomings in their present system and requested assistance from the RTI Biomedical Application Team. The disadvantages of the present system are:

- (1) High cost because it is equipped with an electronic cycling system (for controlled breathing), which is not necessary in the continuous negative pressure technique.

- (2) The negative pressure is applied to the entire body except the head, thus interfering with the infant's cardiovascular function and producing an increase of air in the gastrointestinal tract.

- (3) The nursing care of the infant is very difficult and cannot be given without discontinuing the negative pressure.

To overcome these disadvantages, the University of Miami medical team wished to fabricate a CNP chamber that would cover only the infant's thorax, arms, and upper abdomen. Such a system would offer the following advantages over the use of continuous positive pressure in the airway:

(1) It avoids tracheal intubation and leaves the face free for nursing care. This point is of great importance since, in addition to feeding the infant, it is normally necessary to suck mucus from the infant's trachea at frequent intervals. The CPAP must be discontinued during such nursing care.

(2) Its interference with venous return to the right heart will be minimal.

(3) It avoids the increase of air in the gastrointestinal tract.

The technology employed in the construction of the Lower Body Negative Pressure System (Figures 18 and 19) for NASA's 1973 Skylab mission has direct application in providing therapeutic treatment for respiratory distress syndrome. A Marshall Space Flight Center engineer, Mr. Ted Knowling, visited the University of Miami medical team to consider the applicability of the NASA Lower Body Negative Pressure System to this problem. The major problem to be encountered in the design of the needed CNP system is the air seal that will be required at the waist. (The neck seal that is used on commercially available respirators is thought to be adequate.) The waist seal that was designed for NASA's Lower Body Negative Pressure System appears to provide an excellent solution to the problem of sealing the CNP unit at the infant's waist. Additionally, the NASA seal is adjustable, which will allow the CNP chamber to accommodate infants of various sizes.

A mechanical designer from the University of Miami visited Mr. Ted Knowling at MSFC during August 1972. A preliminary design for the CNP system was worked out at that time. The Department of Biomedical Engineering at the University of Miami plans to fabricate the CNP unit; the problem originator is presently seeking funds for the project.

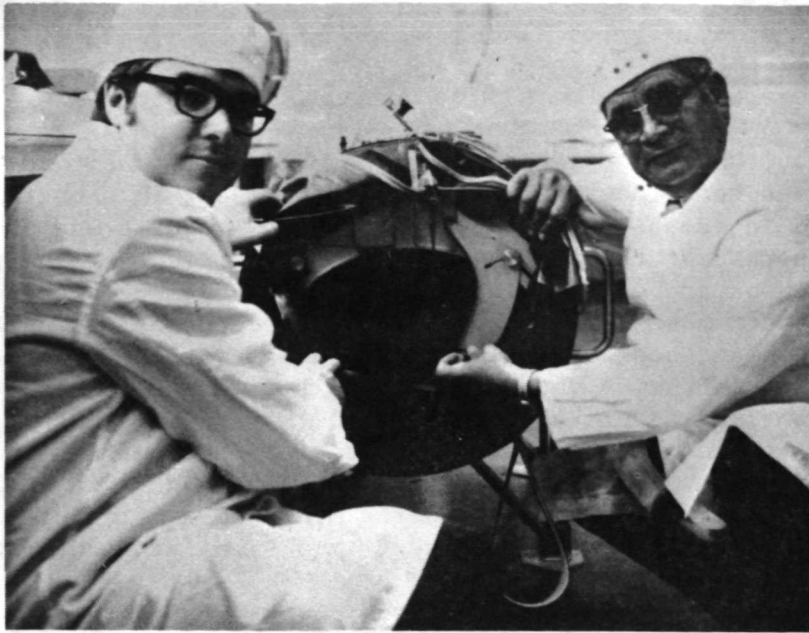


Figure 18. NASA Lower Body Negative Pressure Chamber.

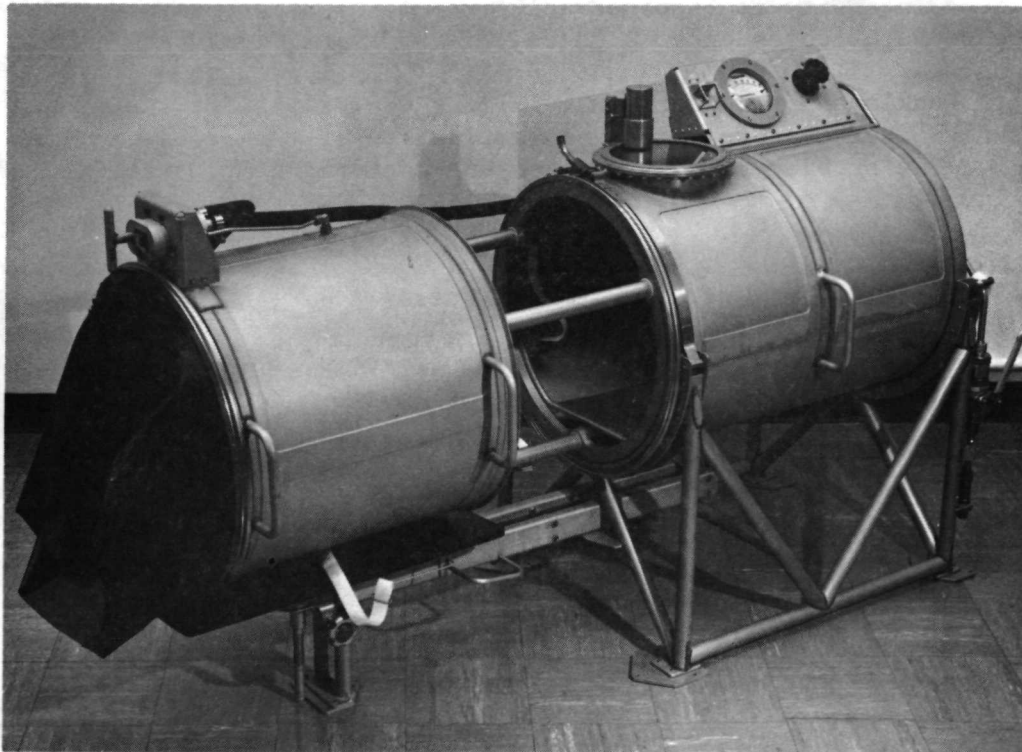


Figure 19. NASA Lower Body Negative Pressure Chamber.

PROBLEM VAM-7 *Bacteria Detection Using Fluorescent Labelling*

Researchers at the University of Miami have identified a type of bacteria that causes tooth decay in laboratory animals. This bacteria has now been found in human beings and is possibly a major cause of tooth decay in man. Fluorescent techniques are employed to discover the presence of this bacteria in human beings. This is possible because of the development of a vaccine that makes laboratory animals produce antibodies to attack the bacteria. These antibodies are labeled with a substance (fluorescein thiocyanate) that makes them fluoresce when excited with ultraviolet light. When the labeled antibodies are applied to a culture having these bacteria, they become bound to the cell wall of the bacteria. The culture is then washed and only those antibodies that are bound to the bacteria remain. Therefore, when the culture is viewed under a microscope using ultraviolet illumination, the antibodies can be spotted, thus signifying the presence of the bacteria that cause tooth decay.

To find out how many of these bacteria are present, all bacteria in the culture are allowed to grow. It was discovered that a second type of bacteria that normally resides in the mouths of human beings exhibits a natural fluorescence. The autofluorescence of the second bacteria complicates the detection of the labeled antibodies. It should be emphasized that the autofluorescence presents a problem only when all bacteria are allowed to grow (i.e., it is only when the autofluorescing bacteria are in colonies that the autofluorescence is of sufficient intensity to be observable). A means of suppressing the radiation due to autofluorescence is needed.

Mr. Larry Dunkleman of Goddard Space Flight Center visited the problem originator and conducted a preliminary investigation of the problem during March of 1972. The problem originator has sent bacteria samples to GSFC for analysis.

PROBLEM VAM-16 *Transmission of Gamma Camera Data*

NASA's communications technology is being employed to design a data transmission system for transmitting gamma camera data from remote hospitals into a university medical center for analysis.

Radioisotopes can be administered harmlessly to a patient if the dose is kept small; thus they have found use in a variety of medical diagnostic and research applications. Radioactive gallium, for example, concentrates in a variety of human neoplasms and is of great assistance to the clinician in locating tumors otherwise difficult to find. A second example of the application of isotopes is the use of a radioactive dye in the heart to aid in the diagnosis of heart ailments. One of the instruments commonly used to detect and image a region of radioactivity is the gamma camera. Gamma camera data is well suited for digital processing (e.g., image enhancement, organ volume and blood flow rate computations, etc.) thus making the gamma camera data of increased diagnostic aid to the physician.

Medical specialists, computing facilities as well as engineering support capable of processing and analyzing the gamma camera data to increase its diagnostic value are available at only a small number of medical centers across the U. S. Gamma cameras, however, are available for taking patient data at many hospitals. Such is the case in the Miami area. Hospitals in the Miami area rely upon the medical staff at the University of Miami School of Medicine to provide competent consultation on a variety of medical problems. Gamma camera data can be taken at remote hospitals but it cannot be adequately analyzed without the University's medical and technical staff. The Department of Nuclear Medicine wishes to design a data transmission system for transmitting gamma camera data from remote hospitals to the University's medical center.

The problem originator visited MSFC to discuss the problem in detail. An engineer from MSFC visited the University medical center and began a systems engineering analysis of the communication requirements for this application.

PROBLEM WF-3 *Prosthetic Valve for Urinary Tract*

A number of different injuries and diseases can result in loss of control of urinary function. Victims of congenital defects, neurogenic bladder diseases, stroke, and multiple sclerosis, as well as war and automobile accident casualties, frequently experience bladder and urethral malfunctions. These malfunctions usually involve an inability to contract the muscles in the bladder wall or an inability to relax muscles that close the urethra; i.e., the passage through which the bladder is emptied. This condition generally results in gradual deterioration of the bladder, infections of the urinary tract, and, in some cases, damage to the kidneys and subsequent death. This condition is the most frequent cause of death of paraplegics. In treating patients who cannot control urinary function, it is important that the bladder be allowed to fill and then be emptied rapidly every 3 to 4 hours. This periodic functioning allows the muscles of the bladder to be exercised and, as a result, to remain healthy. One approach that has been taken is to attach electrodes to the bladder muscles so that contraction of the bladder can be electrically induced by the patient. This electrical stimulation unfortunately also induces contraction of muscle groups--i.e., sphincters--that close the urethra. As a result, fluid pressure inside the bladder becomes dangerously and painfully high.

A valve that can be implanted in the urethra and can be controlled by the patient is needed to successfully treat the loss of urinary function. In cases where bladder muscle is healthy when the valve is implanted, the bladder would contract when the valve is opened without stimulation due to the inherent elasticity of healthy muscle tissue. If bladder muscle deterioration has occurred, electrical stimulation can be used simultaneously with opening of the valve without causing excessive internal pressure.

Functional requirements and constraints on the configuration of the prosthetic urethral valve are as follows:

(1) It is desirable that the valve be cylindrical with a maximum length of 2 cm and a maximum diameter of 2.5 cm. (Small rigid tubes will pass through the physiological valves--sphincter vesicle and external sphincter--shown in the figure so that fluid is held in the bladder only by the prosthetic valve.)

(2) The patient must have manual control of the valve.

(3) The valve must remain closed when exposed to a maximum differential pressure of 150 cm of H₂O.

(4) The valve cannot be controlled through the use of wires or tubes passing through the skin.

(5) All surfaces of the valve that are exposed to tissue must be physiologically inert material, such as silicone rubber.

(6) Functional reliability is an absolute necessity.

The solution to the requirement for a prosthetic urethral valve (Figure 20) is a completely implanted and closed hydraulic system with two stable states. One state corresponds to the valve being closed; in the other state, the valve is open. The open and closed states of the prosthesis are selected by the patient. This is done simply by pressing with the hand on one of two positions of his body. A more detailed description of the operation and construction of the valve is presented in the following paragraphs.

The valve essentially consists of three elements: the urinary valve, a check valve, and a pressure bulb, connected by flexible tubing. The urinary valve consists of an inflatable, rubber diaphragm fitted into a polystyrene tube. The polystyrene tube restrains the diaphragm, so that, when the diaphragm is inflated, the tube is completely sealed. In addition, the polystyrene tube is configured to allow the urethral valve to be securely attached in place.

The check valve, which lies between the urinary valve and the pressure bulb, serves two functions. First, it is a one-way check valve placed so that, when the urethral valve diaphragm is inflated, the check valve is closed, pressurizing the diaphragm and keeping the urethral valve closed. Second, the check valve is specially designed so that slight deformation of the check valve, achieved by applying a small force to the body of the valve, causes the check valve to open. This releases pressure in the diaphragm opening the urethral valve. The body of the check valve is constructed from silicone rubber with a rigid ball preloaded on the seat. Slight pressure applied to the body of the check valve deforms the valve seat so that, instead of having a circular cross section, which can be sealed by a ball, it becomes an essentially elliptical cross section through which fluid can leak around the ball, releasing pressure on the urethral valve.

The pressure bulb is used to apply pressure to the diaphragm of the urethral valve, thus closing it. Both the check valve and the pressure bulb can be implanted beneath and operated through the skin on the patient's side. The two are separated by a flexible tube approximately 4 inches long to achieve unambiguous separation of function.

This system fulfills all of the requirements of the desired prosthetic urethral valve, yet retains a simplicity which should lead to reliable operation. Several features of the valve are particularly important: (1) The entire system can be easily coated with silicone rubber and rendered physiologically inert. (2) No external connections are required to actuate the valve. The simplicity of the check valve permits voiding using only the pressure of one finger on the skin at the appropriate point. Re-inflation of the diaphragm, when voiding is complete, is easily accomplished by pressing with the palm of the hand over the bulb, which is implanted underneath the skin. (3) Because of the simplicity of the system, it should be a highly reliable device. Should the system fail, resulting in loss of pressure to the prosthetic urethral valve, the urinary track would remain open. Thus an immediate emergency operation would not be required, as would be the case if the valve could fail in a closed position. (4) Inflation and deflation of the diaphragm in the urinary valve will result in flexing of the exterior surfaces of the valve that come in contact with the urine. This flexing action will tend to break off any incrustation that might occur, keeping the closing surfaces of the valve clean.

The prosthetic urethral valve has been fabricated under NASA contract by the Biomedical Engineering Department of the University of Virginia. A total of five units were completed. Arrangements have been completed with members of the University of Virginia Medical School for *in vivo* testing of the valves in experimental animals.

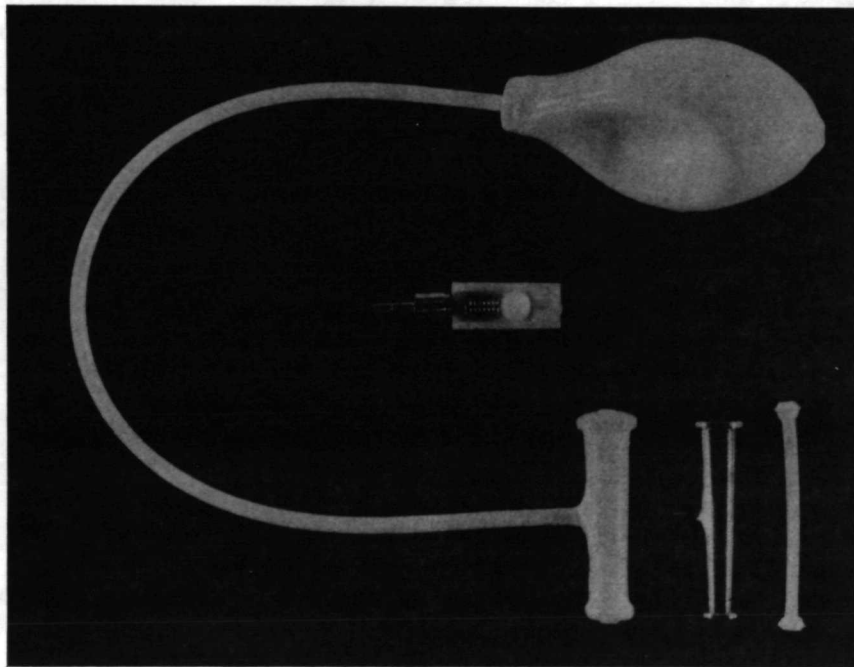


Figure 20. Prosthetic Urethral Valve.

PROBLEM WWRC-7 *A Signalling (Nurse-Call) System for Multiple Sclerosis Patients*

A NASA engineer has designed a call system for multiple sclerosis patients which is being evaluated in a major rehabilitation center.

The Woodrow Wilson Rehabilitation Center (WWRC) of the Virginia Department of Vocational Rehabilitation is planning a new building for the Medical Services Division. Among those who will be housed in the new building are a number of multiple sclerosis patients with severe disabilities. Such patients have little or no use of hands or feet. Consequently, they must depend on the services of nurses for practically all of their needs. Their disabilities are often so severe that they cannot accomplish the relatively simple task (for a person without disability) of operating the call button used in most hospitals to initiate a signalling system.

The patients requiring such a signalling system generally have voluntary control of one or all of the following functions that could conceivably be used for control:

- (1) Breath (respiration)
- (2) Eye movement and blink
- (3) Head motion--the head can generally be raised 2 inches and can be turned from side to side.

Most patients cannot change their positions except for the head so that they remain essentially stationary unless moved by attendants. It is desirable that the signalling system be capable of activation by a patient sitting in a wheelchair beside the bed. Generally, complicated electronic and optical systems of high sensitivity that require frequent adjustment or maintenance are undesirable because of the lack of skilled technicians. On the other hand, if an electronic or optical system of great ruggedness and high reliability could be achieved, it would certainly be given consideration. In summary, a system capable of operation by one of the three control mechanisms available to the patient is required, but ease of maintenance and high reliability cannot be ignored as constraints on this problem. The Southwest Research Institute (SwRI) Team has been working for some time with the Marshall Space Flight Center and the Langley Research Center on a device to permit paraplegics to perform a number of functions from their beds. The system that is being developed employs a breath-actuated switch suggested by personnel at the Langley Research Center along with a logic circuit that permits the patient to control a number of electrically operable devices from his bed. The system being developed for the application identified by the SwRI Team is more complex than that required by the problem at WWRC. The problem at WWRC is merely to call the nurse and, essentially, a substitute for the hand-activated nurse-call button is required.

(See Figure 21). At WWRC a commercially available unit is used to permit communication between the nurse station and the patient by means of an inter-com system. The system is activated by a call button. Although the problem at WWRC does not require the complexity of that required at SwRI, the breath-operated microswitch suggested by LRC as the control element for the more complex system can be used in conjunction with the commercially available system at WWRC. The Langley breath-actuated switch appears to be completely compatible with the current installation at WWRC. This, of course, is a very significant advantage. One of the breath-actuated switches has been obtained for evaluation at WWRC. Should the evaluation prove that the breath-actuated switch is a viable solution to the problem, it is anticipated that WWRC will convert all multiple sclerosis and paraplegic call stations to the use of the breath-actuated microswitch.



Figure 21. Breath-actuated Switch.

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5.0 CONCLUSIONS AND RECOMMENDATIONS

During this reporting period three potential technology applications and four technology applications were accomplished. The source of solution of these problems came primarily from direct interaction between NASA Field Center personnel and Biomedical Application Team personnel. Six of the problems were solved by direct contact with the Field Centers and one problem was solved as a result of a problem statement circulation. This is the first reporting period since the inception of the Team in 1966 that no problems were solved using literature searching. For the past three years the direct interaction with the Field Centers has accounted for approximately 90 percent of the solutions to problems, but usually a small percent are solved using the computerized literature search. Because of the statistically small sample, one should not conclude that information searching is no longer productive but, as in past reporting periods, it contributed relatively little to our total success.

In order for a technology application to be accomplished, implementation of the technology must occur. The means of implementation varies with each problem but for the seven technology applications and potential technology applications reported during this period, the sources have been either expenditure of funds by the problem originator or NASA equipment loan. Four of the problem solutions were implemented by direct expenditure of the problem originator's funds, and three of the problems were solved by NASA equipment loan. This loan of NASA equipment did not require expenditure of NASA applications engineering funds. However, the availability of these funds remains a useful alternative in those cases where the requirements for applications engineering expenditures are met.

The requirements for reports in this program causes a significant expenditure of contract funds. It is estimated that approximately 15 percent of the total contract funds are spent for the various reports such as weekly reports, monthly reports, semiannual reports, and final reports. Therefore, it should be noted that a reduction of report expenditures results in a direct increase in funds available for problem solving and thus an increase in program output.

One of the major lessons learned by the team since 1966 concerns the selection of Biomedical Application Team personnel. Because this individual provides the direct link between the medical researcher and the NASA technology, the success of the program is directly related to his abilities. The team member must have a broad background in engineering and science which allows him to understand the breadth of NASA technology which can be applied to the medical problems. In addition, it is important that the team members have an understanding of the medical problem area with particular emphasis on the significance of the medical problem. Even though technical ability is a necessary condition for success, it is not a sufficient condition. The team member must have certain personality traits that allow him to provide an effective interface between the many people he encounters in a day-

to-day activities. These traits include a gregarious nature, self-confidence, and memory, and a correlation ability. The team member must have those personal traits that will allow him to work effectively in the many areas of expertise which must be brought to bear to solve the medical problems.

One vital lesson learned in the program concerns the need for fast action by every one associated with the program. When fast action occurs, the probability of problem solution is significantly enhanced. A good example of this situation is the potential technology application NCI-13, Portable Isolation Unit. In this problem the team was able to provide the National Cancer Institute with technical information, and a Biological Isolation Garment within three weeks. The National Cancer Institute personnel responded quickly and were able to build a prototype in less than three months from the time of the initial contact with the team. Delays in any phase of the transfer process will inhibit the probability of problem solutions.

When a technology application has been accomplished, a medical problem has been solved for a single medical investigator. If this technology application is to have full impact on society, the technology should be available to other medical research groups. This availability can be directly achieved if a manufacturer for the technology can be found. The problem of finding suitable manufacturers for completed technology applications is a major problem which the Team has attacked in two ways. One way concerns direct interaction with certain industries and the second way is through the formation of the Aerospace Technology Committee of the Association for the Advancement of Medical Instrumentation. Through these activities the team has learned that it is extremely difficult to approach a large company with a prototype device with the expectation that the company will eventually manufacture the device. Efforts in this direction have largely failed. The major interest in this type of activity comes from the small entrepreneurial companies that are aggressively seeking new product opportunities. It has become clear that if the team is to have success in this vital activity, a major commitment of effort will be required. It is recommended that one individual direct his total effort to this important problem area. It is only through an intense concentration on the many aspects of the total problem that the program can achieve success in the commercialization of technology on a par with the success already found in the transfer of aerospace technology to medical problems.

APPENDIX A
PROJECT ACTIVITY SUMMARY

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TECHNOLOGY APPLICATIONS ACCOMPLISHED

TU-3	<i>Lung Sound Detection</i>
MISC-27	<i>Improved Cushioning Material for Protective Helmets</i>
TU-29	<i>Damage to Blood from Microwave Heaters</i>
WF-114	<i>Improved Utilization of Laboratory Computers</i>

POTENTIAL TECHNOLOGY APPLICATIONS IDENTIFIED

NCI-13	<i>Portable Isolation Garment</i>
TU-33	<i>Silica Measurement in Microgram Quantities</i>
VAM-13	<i>Corrosion and Fracture of Orthopedic Implants</i>

IMPACTS

MISC-29	<i>Nurse-Call for Quadriplegic</i>
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CURRENTLY ACTIVE PROBLEMS AS OF 28 FEBRUARY 1973

<u>Problem Number</u>	<u>Status Code*</u>	<u>Problem Title</u>
CP-3	E	<i>Automated Measurements from Coronary Angiograms</i>
DU-31	E	<i>Catheter-Mounted Pressure Transducer</i>
DU-48	E	<i>Urine Flowmeter</i>
DU-74	E	<i>Testing of Neuropathic Patients</i>
EU-12	E	<i>A Rapid Method of Applying EEG Electrodes</i>
EU-19	D	<i>Head Motion Measurement</i>
MISC-6	E	<i>Motor for Powering Prosthetic Unit</i>
MISC-9	B	<i>pO₂ Telemetry Capsule</i>
MISC-20	B	<i>Visual Field Mapping</i>
MISC-23	B	<i>Pattern Recognition of Ultrasonograms</i>
MISC-24	D	<i>Metal pH Electrode</i>
MISC-25	D	<i>Micro-Connector for Magnetically Guided Catheter</i>
MISC-26	B	<i>Rapid Detection of Bacteria</i>
MISC-28	B	<i>A Stronger Protective Helmet for Epileptic Patient</i>
MISC-29	F	<i>Nurse-Call for Quadriplegic</i>
MS-1	B	<i>Hepatitis Detection</i>
NCI-3	F	<i>Blood Pressure Measurement</i>
NCI-4	E	<i>Controlled Rate of Freezing a Liquid</i>
NCI-9	E	<i>Improved Emulsion for Autoradiography</i>
NCI-10	C	<i>Scanning Tumors in Small Animals with Gallium-67</i>
NCI-12	B	<i>New or Improved Methods of Detecting Breast Cancer</i>
NCI-13	E	<i>Portable Isolation Unit</i>
NHLI-1	E	<i>Intramyocardial Stress Measurement</i>
OF-2	E	<i>Bone Density Measurement</i>
TU-3	F	<i>Lung Sound Detection</i>
TU-9	E	<i>Human Voice Analysis</i>
TU-10	E	<i>Quantization of Heart Tissue Hardness</i>
TU-22	E	<i>X-Ray Microplanigraph</i>

*See explanation of status codes at end of listing.

Problem Number	Status Code*	Problem Title
TU-25	D	<i>Blood Damage Measurement</i>
TU-29	F	<i>Damage to Blood from Microwave Heaters</i>
TU-32	B	<i>Calcium Microelectrode</i>
TU-33	E	<i>Silica Measurement in Microwave Quantities</i>
TU-35	C	<i>Subcutaneous Temperature and Power Density Measurement in a Microwave Field</i>
TU-36	D	<i>Analysis of Time Varying Spectral Analysis Data</i>
UNC-63	D	<i>EKG Processor</i>
UNC-66	D	<i>Determining Tissue Perfusion Adequacy</i>
UNC-67	D	<i>Noninvasive Technique for Detecting Heart Valve Deterioration</i>
UNC-70	D	<i>Tantalum Suspension Creation and Delivery System</i>
UNC-71	D	<i>Finger Joint Flexor</i>
UNC-72	D	<i>Retractable Cover for Specimen Catheter</i>
USDA-1	C	<i>Separation of Certain Seeds by Density</i>
VAM-2	E	<i>Diagnosing Gait Abnormalities</i>
VAM-6	D	<i>Negative Pressure Chamber</i>
VAM-7	D	<i>Bacteria Detection Using Fluorescent Labelling</i>
VAM-8	D	<i>Impedance Cardiographic System for Infants</i>
VAM-12	E	<i>Blood Pulse Rate Indicator</i>
VAM-13	E	<i>Corrosion and Fracture of Orthopedic Implants</i>
VAM-14	B	<i>Gas Concentration System</i>
VAM-15	B	<i>Cooling of Metals Under Electron Bombardment</i>
VAM-16	D	<i>Transmission of Gamma Camera Data</i>
WF-3	E	<i>Prosthetic Valve for Urinary Tract</i>
WF-88	E	<i>Accurate Determination of Arterial Pressure Pulse Transit Time</i>
WF-107	D	<i>An Inexpensive Method of Monitoring Respiration in Anesthetized Primates Being Ventilated by Mechanical Respirators</i>
WF-112	B	<i>Method of Correlating Composition with Differences in Surface Morphology of Kidney Stones</i>
WF-115	D	<i>A Means of Detecting the Onset of Shock</i>
WF-116	A	<i>Organ Preservation</i>
WWRC-7	E	<i>A Signalling (Nurse-Call) System for Multiple Sclerosis Patients</i>

STATUS CODE DEFINITIONS

A. Problem Definition

Problem definition includes the identification of specific technology-related problems through discussions with biomedical investigators and the preparation of functional descriptions of problems using non-disciplinary terminology.

B. Information Searching

Information relevant to a solution is being sought by computer and/or manual information searching.

C. Problem Abstract Dissemination

An information search has revealed no potential solutions, and a problem abstract is being circulated to individual scientists and engineers at NASA Centers and contractor facilities to solicit suggestions.

D. Evaluation

Potentially useful information or technology has been identified and is being evaluated by the Team and/or the problem originator.

E. Potential Technology Application

Information or technology has been evaluated and found to be of potential value but has not been applied.

F. Followup Activity

A technology application has been accomplished, but further activity (e.g., documentation, obtaining experimental validation of utility, continuing modification, etc.) is required.

APPENDIX B

DESCRIPTION OF CURRENTLY ACTIVE PROBLEMS (CATEGORIZED BY HEALTH AREAS)

(This description does not include those active problems previously discussed in Section 2 as technology applications, potential technology applications, and impacts.)

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HEALTH AREAS

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MULTIPHASIC HEALTH SCREENING, CLINICAL DIAGNOSIS	B-5
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COMMUNICABLE DISEASE DETECTION AND PREVENTION

PROBLEM MISC-26 *Rapid Detection of Bacteria*

Adequate treatment of infections in children is hampered by the physicians inability to rapidly determine the existence of bacteria in body fluids such as urine, blood, and spinal fluids. Many physicians are commonly faced with a problem of positively determining the nature of an illness when the symptoms point to some type of bacterial infection. These symptoms, unfortunately, are non-specific (fever, headache, chill, sweating, local pain, etc.), and the bacterial infection can be either minor or a quite serious problem such as meningitis, pneumonia, lung abscess, or another major infection. When a physician is faced with a possible serious infection in his patient, he not uncommonly prescribes antibiotics as a safety measure when, in fact, the antibiotics are not required. The excess use of antibiotics is undesirable because of toxic effects of antibiotics as well as development of resistant strains of bacteria. Present methods for detection of bacteria commonly require 12 to 48 hours for positive identification; thus, a detection method which is non-specific and allows detection of bacteria within 30 minutes would be a major asset to the clinical physician.

In a search for a solution for this problem the team has performed an information search and has contacted several Field Centers. The physician is evaluating the information which has been accumulated to date.

MULTIPHASIC HEALTH SCREENING, CLINICAL DIAGNOSIS

PROBLEM MISC-20 *Visual Field Mapping*

The National Institute of Occupational Safety and Health (NIOSH) is concerned with assessing visual requirements and visual degradation associated with various occupational groups. One of the most important factors is the determination of the visual field: the part of the external world that is seen by the eye when its gaze is fixed. The visual field (for white light) of the normal eye subtends an angle of about 160° in the horizontal and 145° in the vertical meridian. Obviously, potential safety hazards exist if one's visual field is not compatible with his occupational environment. While the visual field narrows with age, it is suspected that certain occupational groups may experience more rapid degradation in their visual field because of their working environment.

Perimetry is the term applied to the procedure of mapping out the visual field. The instrument employed is called a perimeter. Perimeters currently in use are capable of determining major limitations of the visual field, but are not

suitable for mass screening in order to assess the occupational factors that contribute to changes in the visual field.

The problem originator is presently reviewing specifications on a vision tester developed for NASA under the IMBLS program.

PROBLEM MS-1 *Hepatitis Detection*

Hepatitis is a inflammation of the liver which can be caused by a number of factors including contaminated water and food, blood transfusions and unsterile instruments. The problem originator is studying this problem in a screening program for children and young adults in a Harlem school population. Many of the problems which contribute to hepatitis are endemic in the ghetto areas of this country, so that screening for hepatitis is of major importance. One commonly used clinical diagnostic tool is the study of yellowing of body tissues such as the conjunctiva (mucous membrane covering the anterior portion of the globe of the eye). At the present time physicians using this technique depend on personal experience in order to adequately diagnose the disease, but a more objective measurement of quantitating the yellowing of tissue is required.

Several field centers have been contacted in an attempt to solve this problem by direct interaction with the field centers.

PROBLEM VAM-14 *Gas Concentration System*

The Department of Nuclear Medicine at the University of Miami is presently installing a cyclotron. One of the benefits to be derived from the cyclotron is the production of various radioactive gases. In particular, they will produce radioactive O₂, CO₂, CO, and N₂. Such radioactive gases have very short half-lives--often on the order of 20 seconds. This permits radiographic studies to be done while incurring a minimum radiation hazard. These gases will be piped to various locations within the hospital. It will be necessary to dispose of the unused gas. While it is possible to allow the unused gas to escape into the atmosphere, the Department of Nuclear Medicine feels that the best approach is to convert the gaseous waste into a liquid waste through a gas concentration system.

A search of the aerospace literature has resulted in some potentially useful information which is under evaluation by the problem originator.

PROBLEM VAM-15 *Cooling of Metals Under Positron and Deuteron Bombardment*

Improved techniques are needed for cooling metals that are bombarded by high intensity positron or deuteron beams during the process of generating radioactive materials. A cyclotron is presently being installed at the Mount Sinai Hospital of Greater Miami. The cyclotron will produce a variety of radioactive

materials which will be employed to conduct radiographic studies as well as to provide radiation therapy for patients. Materials are made radioactive by bombarding them with a positron or deuteron beam. A given metal produces a specific radioactive element. The bombardments cause very high temperatures to exist in the metal in the vicinity of the beam. It is necessary to find a means of dissipating this heat. Contact with a metallurgist at Langley Research Center has been established.

REHABILITATION MEDICINE

PROBLEM EU-19 *Head Motion Measurement*

Damage to certain areas of the central nervous system will produce an excess of excitatory impulses in the nerves going to the skeletal muscles. Such will cause uncontrolled muscular contractions leaving the patient crippled and in much pain. Certain drugs provide some relief, but their effectiveness depends on the muscle spasm cause and where in the control system the drug takes effect.

Currently, at the Georgia Mental Health Institute a number of these drugs are being evaluated. Head motion of patients suffering from spasticity is being measured before and after administration of a particular drug. Evaluation is based on increased range of head motion and improved control.

Patients are placed in a special chair. Their shoulders are fixed in one position by straps. Their head and neck are unrestrained. A helmet is strapped on their head. This helmet is attached to a counter weighted mechanism which provides free movement of the patient's head while providing potentiometer pick offs to measure head motion. Unfortunately, the system is awkward and damps the motion.

The device must be light, less than one half pound (spastic patients have very limited muscular strength). Measurements must be within $\pm 1/2$ degree and capable of unrestricted motion through the entire range of possible head motion with shoulder fixed. It is also desired to be able to trace the path of motion.

A search of NASA produced no acceptable solutions. However, an Institute staff member suggested use of the helmet mounted gun sight system. The problem originator reports that this suggestion is very promising and is being pursued.

PROBLEM MISC-28 *A Stronger Protective Helmet for Epileptic Patient*

A patient suffering grand mal epileptic seizures will normally lose his balance and fall during a seizure. Unfortunately, the normal protective reflexes are inoperative during a seizure. This results in the head impacting the floor, wall, furniture, or any other object in the immediate area with tremendous force. Skull fractures are not unusual. To appreciate the magnitude of the

danger of injury one must realize that it is not unusual for a patient to suffer 20 to 30 seizures in a day's time. In extreme situations this number can go as high as 30 to 35 seizures in an hour's time.

The problem originator is working with several young male epileptic patients. Whenever these patients are not seated or lying down they must wear some type of protective headgear. This is either an automotive or a motorcycle crash helmet. While some protection is provided these helmets are fracturing upon impact. In spite of extensive repairs the helmets must be replaced about once a month. This costs approximately \$1,000 per patient per year. A more durable helmet is desired.

Because of limited muscular strength the weight of the helmet is critical. This eliminates the possibility of beefing up existing helmets or making a helmet of all steel. What appears needed is a material stronger than, but no heavier than, the fiberglass currently used in the finer crash helmets.

MSFC personnel have made several suggestions. These are being investigated along with the possible use of the NASA developed graphite or boron fiber epoxy resins.

PROBLEM UNC-71 *Finger Joint Flexor*

An often encountered task in rehabilitation is the preservation or restoration of mobility to the various joints of the hand. Unfortunately, this task is complicated by several factors:

1. The intense pain experienced by the patient when the joint is moved.
2. A claustrophobic feeling experienced by many, especially the blind, when their hand is enclosed in a device from which they can't free themselves.
3. The skin covering the hand and fingers, as a result of the basic injury, is extremely fragile.
4. The requirements vary in each case, particular joint involved, form of the fused joint, desired motion, etc.

At the North Carolina Memorial Hospital's Hand Rehabilitation Center a device used to cope with this rehabilitation task consist of an inflatable section of motorcycle intertube, a foot operated pump, and a quick release pressure relief valve. By placing the deflated intertube across the palm (in a position similar to that when a normal hand would grasp the tube) then inflation of the tube forces the fingers outward from the palm. Unfortunately, control of the orientation of the pressure applied to the joint is not satisfactory. However, it appears that the use of some inflatable device holds promise.

Langley Research Center personnel submitted an excellent suggestion which describes a simple system for exercising the restricted joints. A prototype is being fabricated for evaluation.

PROBLEM VAM-2 *Diagnosing Gait Abnormalities*

An instrumentation technique suggested by engineers at NASA's Langley Research Center may prove to be a key factor in the diagnosis and quantification of gait abnormalities.

Thousands of Americans suffer loss or impairment of their limb functions. Artificial limbs and therapeutic treatment offer a degree of rehabilitation to many of these persons who are then able to resume many of their normal activities. Presently, gait abnormalities are diagnosed and progress is followed by a physician's visual observation of the patient while walking. The physician has little trouble in determining the type of affliction (e.g., Parkinson's disease, cerebral palsy) by his observation of the patient. However, it is difficult to determine the degree of impairment of gait function. The use of subjective, qualitative information, however well based in elucidated rationale, leaves much to be desired and is usually questioned by those not originating the information. Lack of an objective record is a definite handicap to communications among clinics and even in the same clinic when extended follow-up of a patient is desired. Two primary objectives must be achieved in order to fulfill the needs of orthopedic and rehabilitation clinicians:

- (1) selection of an approach which permits the definition and display of significant parameters of gait in a manner meaningful to clinicians; and
- (2) the appropriate hardware necessary for implementing this approach.

Further, the hardware must be relatively simple, low in cost and should require at best minor modification of existing clinical facilities.

The earliest studies of human and animal locomotion were based upon keen observation and anatomical dissections. Multi-exposure photography was one of the first technologies to be utilized for the gathering of objective data in the late 19th century. Since then, and especially in the past 25 years, efforts have been made to employ a variety of technologies as they became available to the problem of studying human locomotion. Devices such as accelerometers, electrogoniometers, electromyography, high speed photography, strain gauge instrumented force plates have been employed separately or in combination to measure various parameters of human locomotion.

This problem was originally concerned with the application of miniature accelerometers to determine the acceleration of limb segments during walking. The problem was posed to Mr. John Samos, Technology Utilization Officer at

NASA's Langley Research Center (LRC), who contacted an LRC engineer experienced in accelerometer instrumentation. Discussions with this engineer revealed that there were several problems involved in instrumenting a patient with accelerometers and that an alternate approach should be considered. Mr. Samos then contacted Mr. Gordon Bullock and Mr. Bill Howell of Langley's Guidance System Research Section in order to consider new approaches to the problem of human gait analysis. After careful consideration of the problem, Mr. Bullock and Mr. Howell suggested the use of miniature magnetometers which could be attached to the patient's leg (see Figure B-1) to determine the orientation of limb segments during ambulation. A magnetometer is a device for measuring the intensity of a magnetic field. It may be used as a direction sensor since its output is proportional to the cosine between the orientation of its sensing axis and that of a reference magnetic vector. The earth's magnetic field can be employed as a convenient reference vector since, for a given location, it is easily determined and is relatively constant.

The problem originator visited LRC where he received a demonstration of the magnetometer angle sensing technique applied to the problem of gait analysis. Langley Research Center supplied the problem originator with two magnetometers so that a feasibility study could be conducted in a clinical environment. The feasibility study has been completed and the technique appears to hold much promise as a clinical tool for the diagnosis and quantification of gait abnormalities.

DETECTION AND TREATMENT OF HEART DISEASE

PROBLEM CP-3 *Automated Measurement from Coronary Angiograms*

Techniques used to extract information from pictures of Mars will be used to obtain automated information on the performance of the human heart. Medical researchers at Duke University Medical Center developed a technique to determine myocardial contractility of functional character of the cardiac muscle. This technique should be particularly useful in determining effectiveness of surgical procedures designed to improve cardiac function by improving the blood supply to the heart. The technique is thus suitable both pre- and post-operatively to determine coronary revascularization following treatment. The most appropriate surgical procedure of treatment to improve cardiac blood flow, and, in turn, cardiac function, can be determined by this technique that is based upon measurements taken from sequential coronary angiograms.

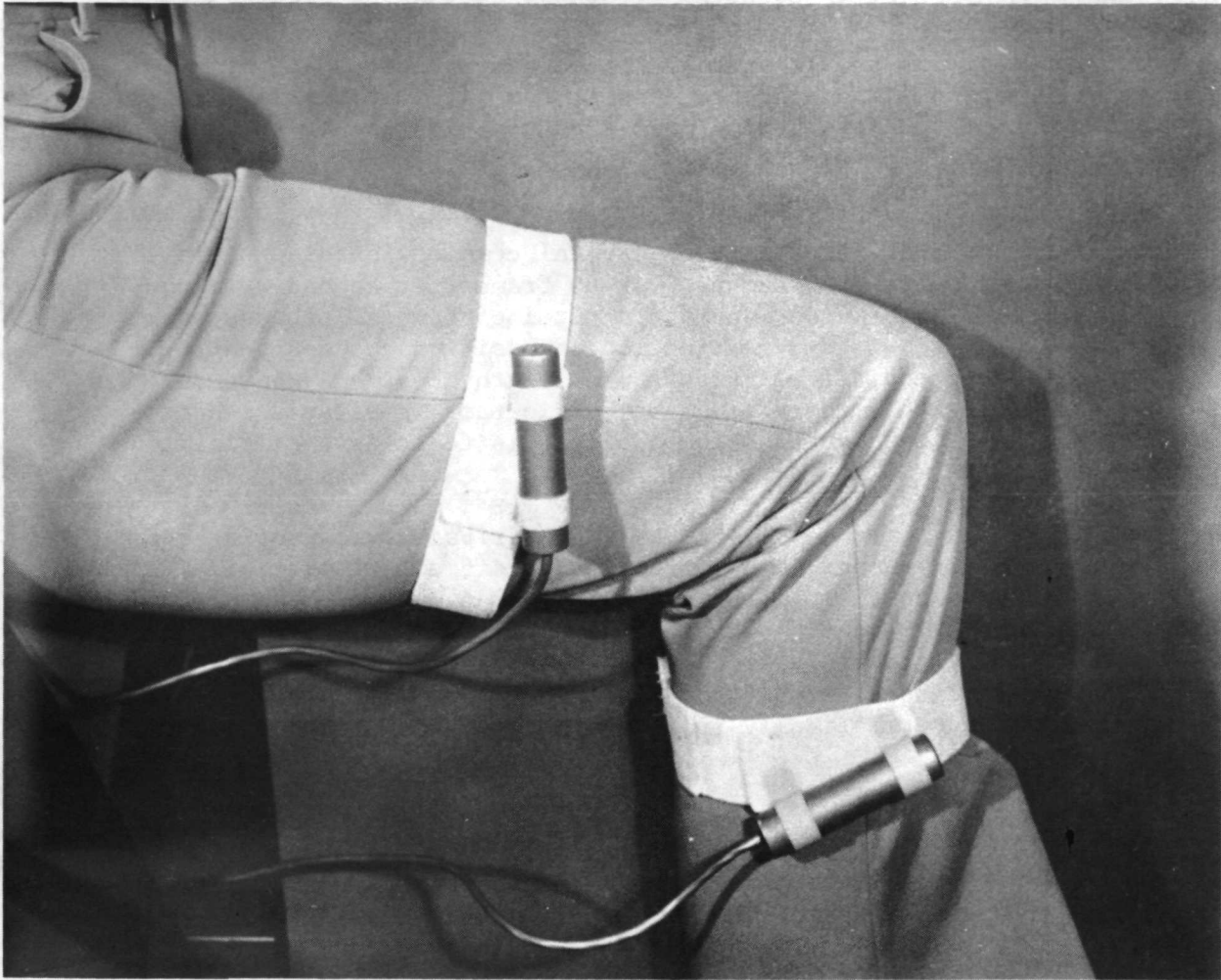


Figure B-1. Miniature Magnetometer and Amplifier
For Sensing Limb Orientation.

A coronary Angiogram is an X-ray image of the heart taken after injection of a radiopaque dye into the coronary artery; this procedure makes the coronary artery and the arterial bifurcations (branching points) visible. The analysis technique above relies on measurements of dimensional changes of various portions of cardiac muscle during a cardiac cycle. These linear dimensional changes can be related directly to cardiac muscle function. The measurement of these dimensional changes is accomplished by measurement of position of specific arterial bifurcations recorded in coronary angiograms. Two separate angiograms are needed, a front-back view and a side view, to determine the location in three-dimensional space of a specified bifurcation. The distance between two bifurcations is a measure of the dimension of the intervening muscle at that instant of time.

At present this procedure is implemented manually. About 20 specific bifurcation points are recorded on the two X-ray views, and the positions of these points are then recorded over several complete cardiac cycles by angiograms exposed every $1/60$ second. At 60 frames per second, two projections, 20 specified bifurcations and a total of several seconds of cineangiograms, the required determination of position changes and their time course is an exceedingly difficult and lengthy task. A reasonable method of automating this analysis of the angiograms is clearly needed if this technique of cardiac function analysis is to achieve clinical importance.

The automated reading of the 35-mm X-ray film strips should provide rapid and accurate information on the positions of specified arterial bifurcations. Accuracy should be compatible with image resolution on the order of 500×500 image resolution elements. It would be acceptable and probably desirable to manually identify (possibly by a light pen or similar technique) on the first film frame the specific bifurcation points to be used, and have the film reading system automatically follow the location of these points in the subsequent frames.

One approach would be to digitize each film frame and apply pattern recognition techniques. This is difficult and probably very inefficient for this problem, however, because at each frame the positions of the 20 or so desired points are already fairly well known from the analysis of the preceding frame. What is needed is a method of identifying and locating these points whose neighborhood values are already known.

The Team determined that the information of interest was at the Jet Propulsion Laboratory. Details of the JPL VICAR software program were given to the researcher and he decided that the enormity of this project required that he work directly at JPL for a short period. Thus, he applied for and received a summer fellowship at JPL for 1970. During this period, he learned the JPL image processing procedures, worked out his own algorithm, and determined that this approach could solve his problem. He then designed

a modified system of image scanning and processing, which was contracted by Dicom Corporation. This equipment has been delivered and is operational.

This significant medical problem will be solved using a modification of the JPL image processing procedures. The equipment is operational, and the actual bifurcation identification has been accomplished over about 15 frames of film. Figure B-2 shows the result of using this technique to identify a region of reduced flow (the circled area in the figure). Additional use of this technique will enable the researcher to automatically dimensional changes in the heart during a cardiac cycle.

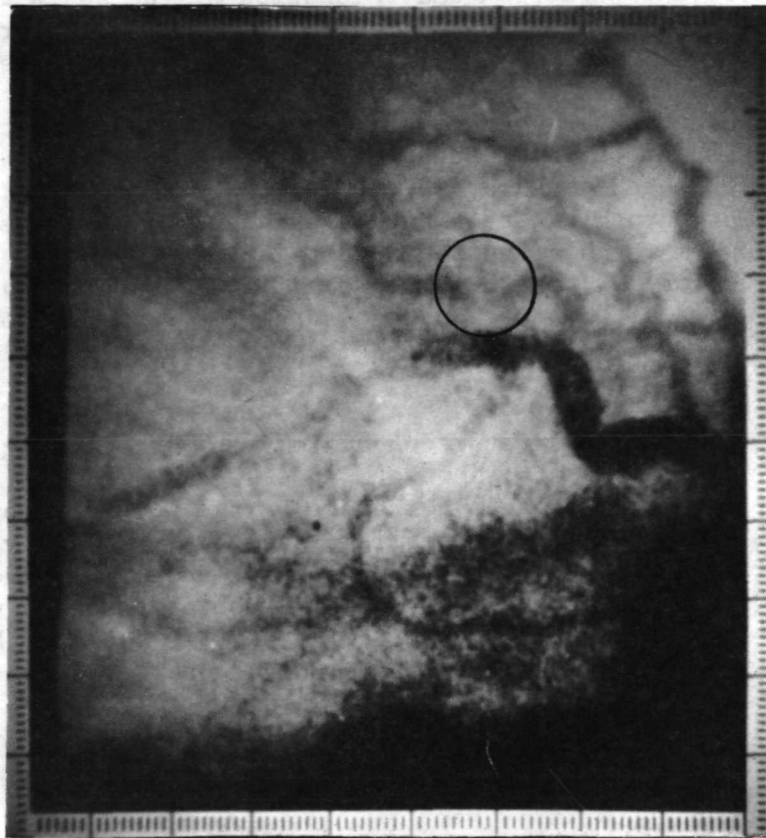


Figure B-2. X-ray of Human Heart Enhanced by Computer Techniques.

PROBLEM NHLI-1 *Intramyocardial Stress Measurement*

A pressure transducer designed by NASA for aerospace use is proving useful in basic heart research.

Myocardial infarction is a process resulting in the death of an area of the heart muscle following a reduction in the blood supply to that area. Acute myocardial infarction is the main cause of premature death in the

population of the developed countries. Myocardial infarction can usually be diagnosed by electrocardiography; however, no method is available for determining the precise location of the affected tissue, which is necessary to assure the success of surgical procedures for repairing the injured muscle.

Since the damaged or dead tissue (whose size and location is dependent on degree of compromised blood supply) results in a "weak area" of the heart muscle, it is expected that a measurement of the forces sustained during the successive contraction and relaxation of the heart will differ from similar measurements made in unaffected areas. The myocardium cannot be treated as a solid, stresses upon any one element can be resolved into three purely compressive or tensile stresses mutually perpendicular to each other. A problem that could be used to make stress measurements within a small region of muscle tissue would lead to a refined location of the region that needs to be removed by surgery. It would also improve our understanding of hemodynamic performance and several other pertinent physiological problems. This should in turn lead to improved surgical procedures and, therefore, to a higher probability of successful recovery for thousands of persons who must undergo surgery for this disorder each year. The physiological assessment might also provide rationale for other therapeutic interventions.

A search of the aerospace literature uncovered many interesting types of pressure and stress transducers; however, none was well suited for the application in question. The Team was aware of two NASA-developed pressure transducers that are significantly smaller than commercially available devices: one developed by Mr. Grant Coon at Ames Research Center, the other by Dr. Wilhelm Rindner, formerly at Electronics Research Center (ERC). The Ames Transducer is potentially applicable to this problem; however, more developmental work is necessary. The ERC transducer appears to offer a possible solution to the problem.

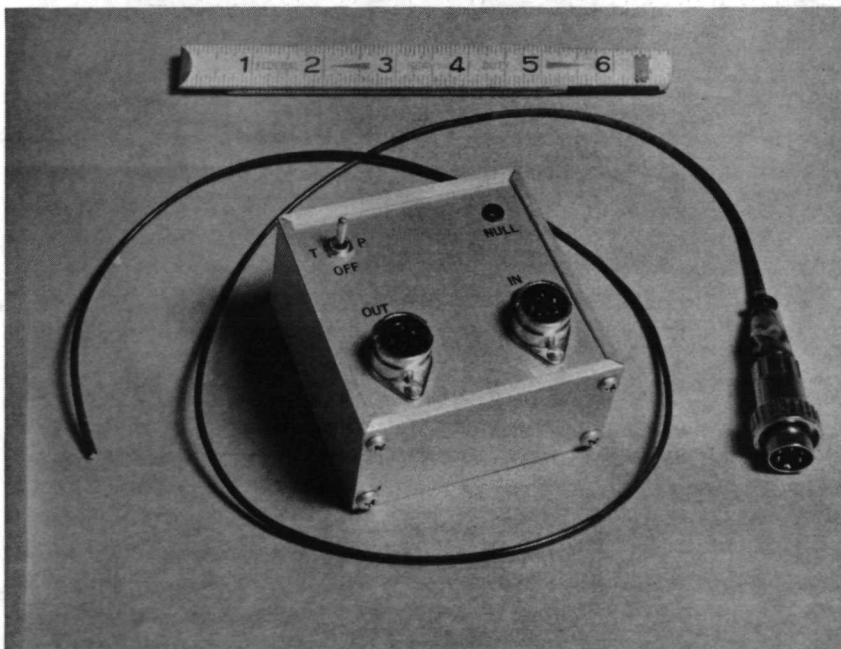


Figure B-3. NASA Pressure Transducer (ERC).

The Team lent an ERC transducer to the problem originator, Dr. Karl Weber, of the National Heart and Lung Institute (NHLI) and assisted in a preliminary experiment with a live animal. Although the preliminary experimental results are not yet fully understood, it is evident that mechanical stress in the heart muscle does undergo changes as the region surrounding the transducer becomes ischemic. Additionally, Dr. Weber has detected changes in the myocardial stress characteristics as the hemodynamic properties of the heart are altered by the administration of certain drugs. Dr. Rindner has provided the transducer in the form of a needle in order to make it somewhat more suitable for probing the heart; evaluation tests are underway (See Figure B-3).

PROBLEM UNC-63 *ECG Processor*

An ECG processor is needed to recognize a specific point of the ECG signal to be used as a gate to record ultrasonic echoes during a preselected interval of the ECG.

Ultrasonic techniques are finding increasing use in the medical field. Perhaps one of the most important uses of ultrasound in medicine has been cardiology. By making modifications to an existing ultrasonic system, the Department of Nuclear Medicine at the University of North Carolina will employ ultrasound to detect cardiac tumors, to study valve anatomy, and to diagnose pericardial infusion with more accuracy than is presently possible.

Commercially available ultrasound systems are designed to produce echo images by displaying on a storage CRT the echoes from pulses transmitted at a constant rate. If the object being imaged moves, then the image on the CRT is blurred. Thus, the problem of imaging a moving heart is complicated. The problem originator wishes to employ a stroboscopic technique when imaging the heart by recording images during only a preselected interval of the patient's ECG. This will insure that the heart is in virtually the same position each time the echoes are recorded. Since the ECG is to be employed as a gating signal, it is necessary to process the ECG in order to recognize the beginning of each heart cycle. A processor that will recognize a specific point on the ECG signal (e.g., the peak of the R wave) is needed. The processor should be relatively immune to baseline shifts in the ECG as well as artifacts. A NASA R-wave detector is under evaluation.

PROBLEM UNC-67 *Noninvasive Technique for Detecting Implanted Artificial Heart Valve Deterioration*

Cardiac valve replacement is a well established surgical procedure. However, it is recognized that the implanted valve prosthesis is subject to a number of failure modes. Wear and deterioration, for example, produce

suboptimal closing and opening characteristics thus reducing the cardiac output. Blood clots, tissue interference, and leaks around the valve mounting are other failure modes. Any of the modes can produce a catastrophic valve failure which will result in almost certain death. Valve repair or replacement can be accomplished in most instances if the condition is detected soon enough.

There are several different valve designs in use. The problem originator is primarily interested in the Lillehei-Kaster Pivoting Disc Prosthesis. In this particular design the disc movement is distinct and relatively large. It is desired to have some noninvasive technique to measure this movement, or some other parameter, which will give an indication of the initial signs of valve malfunction.

A problem statement was distributed. Several excellent suggestions have been received and are being pursued.

PROBLEM VAM-8 *Impedance Cardiographic System for Infants*

In order to better diagnose and treat infants with congenital heart defects, researchers at the University of Miami are experimenting with a NASA-developed impedance cardiographic system. This system was developed to provide a simple, bloodless method of monitoring various parameters of cardiac function of adults without penetrating the skin. The system employs four circular, flexible, metallic electrodes, which are attached to the patient: two around the neck and two around the upper abdomen. University of Miami investigators wish to be able to use this system to measure cardiac parameters of infants; however, the neck electrodes that were designed for this system are inadequate for infants. It is necessary to find a means of employing the existing system with infants. If this system can be used with infants, the next step will be to determine whether useful measurements can be made on children with congenital heart defects.

PROBLEM WF-88 *Accurate Determination of Arterial Pressure Pulse Transit Time*

In the arterial system, the pressure is a function of distance and time; hence it has wave properties. The wave speed of the pressure pulse is related to the elastic modulus of the arterial wall. In addition, wave reflections that occur in the arterial system perturb the pressure function. It is known that the elastic properties of the arterial wall change in humans with age and arterial disease. The biological problem is to detect changes in the material properties of the arterial vessel nondestructively early in the process of arterial disease. Change of the properties of the arterial wall are thought to be related to wave speed or transit time of the arterial pulse.

If the relationships between arterial wall properties and transit time or wave speed measurements of the arterial pulse could be established using improved instrumentation or improved analysis techniques, it would be an important contribution to diagnosis of arterial disease.

The primary requirement of this problem is to determine arterial pressure pulse transit time. Determination of this parameter to a precision of $\pm 5\%$ is required. As secondary requirements, it is desired to be able to obtain information about the material properties of the arterial vessel such as characteristic impedance, terminal impedance, etc.

This problem can be solved using a Pitran Pulse Detection System developed during the summer program at Goddard Space Flight Center (GSFC). The problem originator has built a duplicate of the GSFC unit and tests are underway. The unit is shown in Figure B-4.

PROBLEM WF-107 *An Inexpensive Method of Monitoring Respiration in Anesthetized Primates Being Ventilated by Mechanical Respirators*

As part of a long-term study program into atherosclerosis, the Bowman Gray School of Medicine is involved in a project using primates as experimental animals. Some animals will be fed normal diets while others will be fed atherogenic diets. During these studies it will be necessary to surgically implant a number of devices for monitoring various physiological parameters. During the surgical procedures, the primate will be anesthetized and respired using a positive displacement animal respirator. A tracheal tube inserted into the animal's throat is used to connect the animal to the respirator. It is important, of course, that the animal be properly respired during these surgical procedures. Any interruption of the air flow supply to the animal will result in its death. These animals are specially prepared and represent a significant investment of funds and researcher time so that the loss of even one animal as a result of improper respiration is significant. In order to eliminate this possibility, a technique or method of monitoring the respiration of the animal is desired. A visual indication of the normal respiration of the animal is desired. For example, a meter could be used to provide a varying amplitude indication proportional to the respiration of the animal. For example, inspiration could represent a zero reading, and expiration a positive reading, so that the meter would fluctuate between zero and some positive reading during a normal inspiration/expiration cycle.

The respirator-alarm system using telemetry techniques developed at the Ames Research Center appears useful in this application. The requirements in this problem, however, are significantly simpler so that complicated telemetric equipment is not necessary. In addition, the requirements for an alarm are not necessary. The fundamental requirement is for a meter reading to indicate inspiration and expiration. It is felt that a modification of the Ames

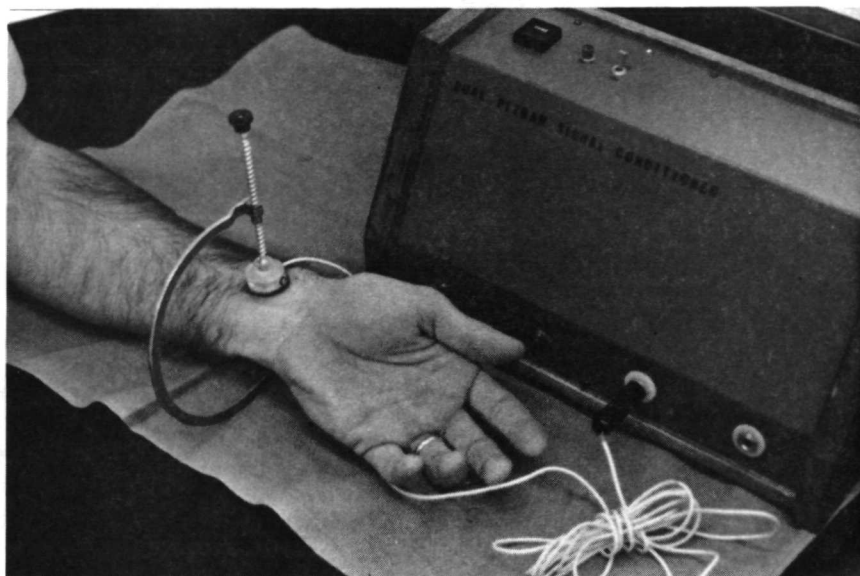


Figure B-4. NASA Pitran Pulse Detection System.

circuitry can be accomplished to provide the required monitor at a very low cost. The Biomedical Engineering Department at Bowman Gray School of Medicine is evaluating the Ames circuitry and modifying the system to this application.

DETECTION AND TREATMENT OF CANCER

PROBLEM MISC-23 *Pattern Recognition of Ultrasonograms*

Tumor detection at an early stage is a critical factor in the successful treatment of the disease. In general, the chances for cure are dramatically improved if the cancer is detected at a very early stage. Conversely, if the tumor is significantly advanced at the time of detection, little chance for cure exists. One new method being explored for tumor detection in the eye is the ultrasonogram. Basically, this consists of a scan of the eye using ultrasonic energy and a display on an X-ray tube. Although visual observation of an ultrasonogram allows one to distinguish a tumorous eye from a normal eye, a more precise method of pattern recognition is required in order to detect smaller tumors. The basic problem is to determine the subtle differences in ultrasonogram patterns of a normal eye and a tumorous eye using some scanning process and automatic pattern recognition technique. The normal eye has a diameter of about 24 millimeters and tumors as small as 3 millimeters must be detected.

The National Aeronautics and Space Administration has broad experience in the area of pattern recognition, and it is felt that this problem is amenable to solution using advanced pattern recognition techniques. The NASA document files are now being carefully studied to determine whether applicable techniques exist.

PROBLEM NCI-9 *Improved Emulsion for Autoradiography*

Knowledge of photographic emulsions by a NASA researcher may improve the emulsions used in the autoradiographic study of cancer.

The study of cancer in experimental animals can be facilitated by labeling the cells with radioactive tritium. The tritium attaches itself to the DNA molecule, and the division of the tumor cell produces new labeled cells. A process called autoradiography detects a radioactive cell by placing a film of photographic emulsion over the cell and exposing the emulsion by the radioactivity. Existing emulsions require an exposure time on the order of months. If a much faster film can be developed, then this technique can be used clinically in following the progress of human cancers. This will provide a valuable new technique in the fight against human cancer.

A computer search of the literature on nuclear emulsions revealed that scientists at Goddard Space Flight Center had employed sounding rockets carrying nuclear emulsions to study the composition and energy spectra of low energy cosmic rays. The TUO at GSFC was presented with this problem and suggested that the Team contact Dr. Jacob Trombka who is quite knowledgeable in this field. Dr. Trombka has experimented with several types of specifically prepared noncommercially available emulsions that will reduce the required exposure time. A Team member met with Dr. Trombka and he discussed these techniques at length. The National Cancer Institute subsequently contracted with a research team at Duke University to undertake a study to develop improved emulsions. Dr. Trombka has been in frequent contact with the Duke team and his ideas will be implemented and evaluated.

PROBLEM NCI-10 *Scanning Tumors in Small Animals with Gallium-67*

An analytic technique developed for aerospace radiation detection is being considered for scanning tumors in animals.

Gallium-67, a radioactive isotope, possesses the special property of concentrating in various types of tumors when administered orally or intravenously to a patient. The mechanism of gallium uptake is not well understood; it is not known whether there is a direct binding of gallium in the tumor tissue or binding to some other agent that, in turn, is concentrated by the tumor. Whichever is the case, Gallium-67 appears mainly in viable rather than necrotic tumors. In addition, studies indicate that Gallium-67 is superior to other commonly employed tumor-scanning agents in absolute tumor concentration and in ratio of tumor to normal tissue concentration. These observations are possibly the most significant recent developments in nuclear medicine.

By administering Gallium-67 to a patient and scanning the body with an instrument that will detect the presence of radioactive substances, the location as well as the size of a tumor can be determined. Radiologists currently employ a variety of camera and scanning systems that are useful in locating tumors in human beings but are relatively ineffective in studying the response of the tumor to therapy. In order to follow tumor growth on a day-to-day basis, a high resolution scanning system that is sensitive to Gallium-67 is needed. In particular, the scanning system should be suitable for scanning the entire bodies of small experimental animals. Such a system would offer a unique opportunity to study methods of inhibiting or retarding tumor growth.

A solution to this problem was proposed by Dr. R. T. Siegel, Director of the Space Radiation Effects Laboratory (SREL), which is operated by the College of William and Mary under support from Langley Research Center. Dr. Siegel's suggestion was experimentally evaluated but found to have inadequate sensitivity. A problem statement has now been circulated to the NASA field centers.

PROBLEM NCI-12 *New or Improved Methods of Detecting Breast Cancer*

Breast cancer is common: 5-6 percent of all women will at some time in their lives develop breast cancer. If cancers are discovered when they are still localized, the majority of them can be cured by surgery and radiotherapy. Provisions for earlier and more comprehensive treatment of patients with breast cancer require improved techniques for detecting malignant tissue during the initial stages of growth. Four techniques for detecting breast cancer are in use at present: physical examination, thermography, xerography, and mammography.

None of these techniques is sufficiently reliable. A combination of these methods provides an improved probability of detecting breast cancer; however, none of the methods provides conclusive results. Each of the methods has shortcomings. New or improved methods, techniques, or approaches for detecting breast cancer at an early stage are needed.

A problem statement was circulated to the NASA field centers and the Team received two suggestions that warranted additional investigation: (1) the use of liquid crystal thermography to obtain visualization of the temperature patterns of the breast with minimum effort and cost, and (2) vibrational methods for detecting tumors deep under the skin surface.

These suggestions were evaluated by a member of the National Cancer Institute's Detection and Diagnosis Subcommittee. While there was some merit in both suggestions, there was no reason to believe that these techniques would offer an improvement over methods presently in use. The Team plans to assist on specific problems encountered in improving existing breast cancer detection techniques.

PROBLEM TU-22 *X-Ray Microplanigraph*

An aerospace method used for analysis of printed circuit boards is being applied to obtain improved X-ray techniques of cancer detection.

Cancer is the second largest cause of death in this country and, according to a recent survey, is the disease most feared by the American people. The state of cancer treatment today is such that generally those cancers that are found early can be successfully treated. The easiest cancers to detect are those that are on the surface of the body, and those most difficult to detect are those deep within the body. Thus, cancers arising deep within the body usually result in the death of the patient because detection of the cancer occurs too late.

It is desirable to develop an instrument capable of detecting tumors deep within the body. In addition, it is desirable to be able to determine whether or not the tumor is malignant or benign and the extent to which the tumor has spread. One common method of detecting tumors is by X-ray. Unfortunately, when the entire body is X-rayed, small tumors cannot be detected because the background level of signal of the X-ray is vastly increased by the thickness of the body. It would be highly desirable to develop a technique whereby X-rays could be made of lamina regions only. If X-rays could be made of thin

laminae, smaller tumors could be detected. The basic problem then is to develop a method whereby X-rays of thin laminae can be made of a patient instead of the conventional X-ray technique.

The technique of making X-rays of thin laminae with high resolution is called X-ray microplanigraphy. This technique has been theoretically possible for many years. Recently, a development in NASA has significantly increased the possibility of developing such a technique. NASA developed such a technique for inspecting multilayer printed circuit boards layer by layer with a resolution of 0.001 inch. This technique has been well developed by a NASA contractor at Illinois Institute of Technology. Basically, it involves moving the X-ray source and detector in a particular geometrical arrangement in such a manner that only thin laminae are measured. The work was funded by MSFC, and the Team was apprised of the work through a computer search. The Team then contacted MSFC for additional information and was referred to the IIT investigator. The problem originator has discussed this technique in detail with the NASA contractor and has decided that this work is highly relevant to his investigation. An example of the use of the technique is shown in Figure B-5.

The device has been implemented at the Tulane School of Medicine. The researcher indicates that tests to date have shown that it is possible to distinguish malignant from benign lesions in the breast. This will eliminate the need for much surgery in cases of suspected breast cancer.

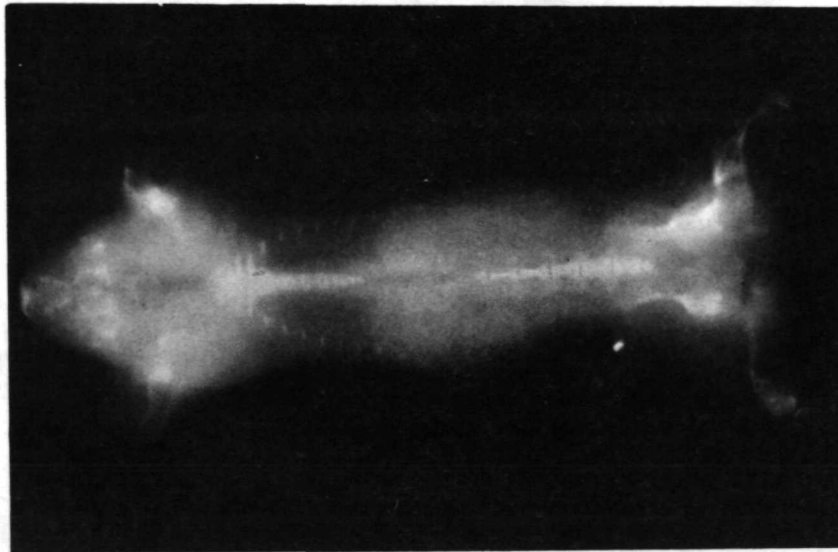


Figure B-5. X-ray Microplanigraph of a Mouse.

PROBLEM WF-115 *A Means of Detecting the Onset of Shock*

This problem has a companion one to problem NCI-3, Automated Blood Pressure Measurement of Critically Ill Patients, which is discussed in section 3 of this report. In both problems the solution is some measure of the onset of shock which will allow corrective action to be taken early enough to prevent the development of irreversible shock which results in death. One method of solving this problem appears to be the use of the NASA oximeter which was developed at Ames Research Center. Initial tests on the use of this device were conducted at the National Cancer Institute and are now being conducted by the problem originator at the Bowman Gray School of Medicine. An application engineering request has been submitted to NASA Headquarters for the development of a second generation model of this device.

ECOLOGY

PROBLEM TU-9 *Human Voice Analysis*

An aerospace technique for improving speech transmission from aircraft is being applied in analyzing speech defects.

Approximately 6-7 percent of the population is considered to have either temporary or chronic speech defects. In chronic cases, inadequate understanding of the causes of speech defects hampers treatment. For example, one speech defect is characterized by a pitch that is either too high or too low and can be caused by contact ulcers, polyps, polypoid degeneration, or chronic laryngitis.

A technological impediment exists in the analysis of speech defects because of the inability to precisely quantize characteristics of the human voice. This is further complicated by the fact that many changes in the human voice are easily detected by the ear but are often quite subtle in their spectral density or frequency changes. A number of techniques have been employed in an attempt to quantize the human voice, but to date no technique has been found that permits the therapist to measure changes in the human voice before and after therapy.

Speech consists of a broad fundamental frequency and many harmonics. Small shifts in fundamental frequency and amplitude cause large changes in the human voice. Frequency spectrum analyses must be able to detect fundamental frequencies that range from as low as 50 Hz for low-pitched male voices to more than 400 Hz for high-pitched children's voices. The technique must measure fundamental frequencies to a precision of 1 Hz and amplitude to a precision of 1 db. The analysis technique must take into account both fundamental frequency and harmonics and their relation to the fundamental frequency. Although not required, real-time analysis is desirable.

Spectral analysis techniques developed by the NASA Michoud Assembly Facility may be applicable to this problem. The problem originator is now discussing the applicability of these techniques with the cognizant NASA personnel.

KIDNEY DISEASE DETECTION AND TREATMENT

PROBLEM WF-112 *Method of Correlating Composition with Differences in Surface Morphology of Kidney Stones*

This problem is related to and, indeed, has been identified as a result of previous work on biomedical problem WF-98, "An Improved Technique to Yield Precise Information on Surface Morphology of Kidney Stones." Under this previous biomedical problem, a number of kidney stones were analyzed by means of scanning electron microscopy at the NASA Marshall Space Flight Center. In this study it was desired to identify the micromorphology of kidney stones of various types and to attempt to correlate the morphologic characteristics of kidney stones with various crystalline types. It was specifically desired to determine whether or not surface morphology is a factor in kidney stone formation.

Information obtained as a result of the cooperation of NASA personnel at the Marshall Space Flight Center is providing for Dr. Boyce a number of scanning electron micrographs of various characteristic kidney stone types has been extremely useful in Dr. Boyce's studies. The scanning electron microscope studies, however, indicated that there are certain lamellar characteristics on the kidney stone surfaces observed. These surface characteristics showed up in many of the scanning electron micrographs as striations on the surface. In order to probe further into the mysteries of kidney stone formation, Dr. Boyce has considered it extremely important to determine whether or not these striations or lamellar-appearing variations on the scanning electron micrographs are related to compositional changes of the kidney stone itself. Consequently, Dr. Boyce wishes to compare certain kidney stones using scanning electron micrographic techniques on the same kidney stones to determine, using the best available techniques the microcomposition of the kidney stone surface. Essentially, a method of obtaining the microcomposition (the composition of portions of the kidney stone surface 1 or 2 micrometers in diameter) of kidney stones is desired to permit comparison of the surface morphology with composition. The possession of this information will provide an answer to the question of whether the lamellar-like structures, shown on many of the kidney stones, are actually associated with compositional differences in the kidney stones.

The scanning electron microscope laboratory at the NASA Marshall Space Flight Center is being fitted with an electron microprobe. This unit will permit measurement of certain elements of the kidney stones. Measurements of composition of areas down to 1-2 micrometers in diameter can be made. Sampling of such small areas of the stone's surface will permit correlation of compositional data with morphologic data as obtained with the scanning electron microscope. A request has been made to Mr. Juan Pizarro, Technology Utilization Office, Marshall Space Flight Center, for assistance on this problem with positive results. Dr. Boyce is presently preparing the kidney stones for processing at Marshall Space Flight Center.

PROBLEM WF-116 *Organ Preservation*

Work relating to organ transplantation is proceeding along three lines of investigation: surgical techniques, procurement of vital organs, and the rejection phenomena. This problem is concerned with organ preservation techniques. In the past, emphasis has been directed primarily toward renal preservation; however, attempts at storing the heart, lungs, liver, and intestines have also been reported. While several complex in vitro preservation techniques have been suggested and employed, they have not significantly increased organ storage duration relative to the most elementary schemes, e.g. placement of the organ in an ice slurry. A kidney, for example, can be conveniently stored in an ice slurry for two to three days. The problem of organ transplantation becomes one of logistics. The renal transplant candidate can presently be maintained in good health at the transplant center if placed on artificial dialysis. When a potential organ donor is located, it is necessary to remove the organ, preserve it in some convenient manner, and transport it to the recipient. Delays between organ removal and storage are undesirable. Ice slurries are currently made by super-cooling a solution of sodium chloride in water. The super-cooled liquid becomes a slurry upon agitation; a skilled physician assistant can therefore make the necessary slurry by slowly pouring the super-cooled sodium chloride solution into a chamber. Frequently, the solution solidifies inside the bottle and is therefore unusable. Most important, it is necessary for the surgical team that removes the donor's organ to have a supply of the super-cooled sodium chloride solution on hand. Medical centers which are accustomed to removing and storing organs for transplantations would not normally be prepared to store an organ while awaiting transport to a recipient. A portable device for making the ice slurry which can be rushed to the donor's locations would solve many of the problems of viable organ procurement.

The Team is currently contacting NASA field centers to identify technology related to this problem.

RESPIRATORY DISEASE DETECTION AND TREATMENT

PROBLEM UNC-70 *Tantalum Suspension Creation and Delivery System*

The respiratory system is composed primarily of soft tissue. Resolution of x-rays of this type of tissue is poor. As a result the usefulness of x-ray in respiratory disease detection is limited.

Several techniques are being explored as possible methods of circumventing this problem. One method makes use of a fine powder composed of tantalum particles (particles are 5 to 10 microns in diameter). The patient breaths

an atmosphere containing a reasonably uniform suspension of these particles. Depending on particle diameter, certain sections of the respiratory airways are coated with tantalum dust. The coated tissue is thus made more x-ray opaque, increasing x-ray resolution.

A satisfactory technique for creating and delivering this uniform suspension to the patient has not been worked out. The problem originator mixes the tantalum powder in water, using a wetting agent, then atomized this slurry with a Bird Space Technology's micronebulizer. The difficulty experienced with this method is that the particles tend to stick together forming clumps. The resulting tissue coating is not uniform and x-rays are spotty.

Currently, several suggestions from Langley Research Center are being investigated. They appear very promising.

PROBLEM UNC-72 *Retractable Cover for Specimen Catheter*

Effective treatment of respiratory infections often requires an accurate identification of the involved organisms. To obtain this identification, a specimen from the infected area is obtained by introducing a specimen catheter through the mouth and throat into the trachea. Unfortunately, organisms present in the mouth and throat can easily be picked up by the catheter as the catheter is passed through these areas. This very likely results in an erroneous typing of the organisms in the trachea.

Some method is needed which would cover the catheter during insertion. Once the catheter is in place the cover would be retracted. During this uncovering process, organisms attached to the cover must not be allowed to contaminate the specimen catheter.

The catheter's outside diameter is 3-4mm, and its length is 18-20 inches. Any material used must be nonirritating to the tissue of the mouth, throat, and trachea.

Langley Research Center personnel submitted two suggested solutions. Both are being evaluated.

IMPROVED SURGICAL PROCEDURES

PROBLEM MISC-25 *Micro-Connector for Magnetically Guided Catheter*

Researchers at Massachusetts General Hospital are developing a system to aid in guiding a catheter to various locations in the cardiovascular system. This system is expected to provide a non-surgical means of correcting certain cardiovascular disorders that are now correctable only through surgery. One

of the procedures which is now being employed in experimental animals requires that a latex balloon be inflated and deposited in an artery. The balloon is guided to the proper location and then inflated by the injection of serum albumin through the catheter. Should the patient show untoward effects or the balloon be found to be improperly positioned, the balloon must be quickly deflated and withdrawn. If the balloon is positioned properly, the ferromagnetic catheter tip is heated by an external R.F. field which causes localized hardening of the serum albumin thus sealing the balloon. The catheter is then withdrawn leaving the balloon in the artery. The balloon simply slips off of the tip of the silicon catheter. It is felt that heating the ferromagnetic tip could be done simpler and less costly by providing a small heating element inside the tip. In this case it appears necessary to employ a miniature electrical connector which disconnects when the catheter is withdrawn. Technological assistance is needed in designing and fabricating such a device. This idea is suggested only as a possible approach; alternate approaches to sealing and detaching the balloon should be considered.

The solution to the problem of sealing and detaching the balloon should satisfy the following requirements:

- 1) The technique should permit the balloon to be pre-tested and must permit the balloon to be deflated if it is improperly positioned.
- 2) Sealing and detaching must be done without allowing any substance in the catheter which would be harmful if spilled into the blood stream.

An engineer at Langley Research Center has suggested an approach to the problem which is presently under evaluation.

PROBLEM TU-25 *Blood Damage Measurement*

Recent medical developments in oxygenators have improved the probability of patient support in cases where temporary assistance in lung function is required. Examples of such use include infants with certain diseases and adults with crushed chests due to accidents. Some damage to the blood results from oxygenators, and a new means of measuring blood damage is required. Existing tests usually consist of hemolysis analysis.

Possible measurement techniques include partial pressure O_2 and CO_2 , cell mass, lactate/pyruvate, plasma hemoglobin, protoglobulin, serotonin, and platelet damage.

A useful enzymatic technique was disclosed by a problem statement circulation. The technique, developed for use on the Skylab mission, will be implemented when a current grant request of the problem originator is funded.

PROBLEM TU-36 *Analysis of Time Varying Spectral Analysis Data*

In problem TU-3, Lung Sound Analysis, a technique was developed for measuring pulmonary sounds using real-time Fourier analysis. A two-dimensional display of real-time information on an oscilloscope permits the physician to obtain new diagnostic information. Research using this technique revealed that some means of recording the real-time data as a function of time was required in order to record subtle changes in pulmonary sounds. Thus, a means of providing a three-dimensional display of the variables, time, amplitude, and frequency are required.

This problem can be solved using a three-dimensional display similar to that used for display of electrocardiograms at Manned Spacecraft Center. This widely used technique appears to be applicable, and a manufacturer has been asked for quotation on the fabrication of a special purpose switching device which will accomplish the task.

BASIC MEDICAL RESEARCH PROBLEMS

PROBLEM MISC-9 *pO₂ Telemetry Capsule*

Diarrhea may be due to various causes ranging from acute infection to psychogenic factors. Current research indicates that bacteria that normally reside in the mouth can, under certain conditions, give rise to diarrheal states. There are two types of such bacteria: one that must have oxygen to live and another that cannot thrive in the presence of oxygen. Oxygen exists in the gaseous state throughout the digestive tract and must remain relatively constant to provide for the proper balance of bacteria.

In order to learn more about the conditions that give rise to diarrhea and to evaluate the use of antibiotics in altering the oxygen content of the digestive tract, this researcher would like to measure the partial pressure of oxygen in the lumen of the gut at various points. This problem has baffled researchers for several years.

The researcher feels that the best solution would be a swallowable capsule for measuring the telemetering the partial pressure of oxygen as it passes through the gut.

A search of the aerospace literature failed to uncover a solution to this problem. The Team's efforts led to the discovery of an industrial research group that had developed a pO₂ telemetry capsule for marketing purposes. It was decided that, because of its limited market potential, the pO₂ telemetry capsule would be pursued no longer by the industrial concern. The developers of the pO₂ telemetry capsule made available to the Team the schematic diagram of the device as well as test results that will allow the problem originator to begin a developmental program in this area.

PROBLEM TU-10 *Quantization of Heart Tissue Hardness*

Techniques developed to study aerospace materials have been used to study the human heart during pathological examination.

Examination of the various organs of the human body following death can reveal not only the cause of death, but other conditions affecting the person at the time of death. Research at the Tulane University School of Medicine has shown that a peculiar softening of the heart tissue can be seen in some patients that did not die of heart disease. The cause of this unusual softening is not known, but a number of factors are believed to be important. For example, there appears to be an infarction and a definite softness in the heart tissue. The reasons for this are being sought in experimental work using rats in which the blood is cut off temporarily from portions of the heart in order to discover the changes in the heart tissue. Simultaneously, studies are being conducted on human hearts in autopsy examinations to determine whether this soft region can be attributed to any known condition of the human being prior to death. In order to carefully characterize these soft regions, a means of measuring softness of the heart tissue is required. The researcher has attempted to use a conventional eye tonometer for this purpose but the results have not been reproducible.

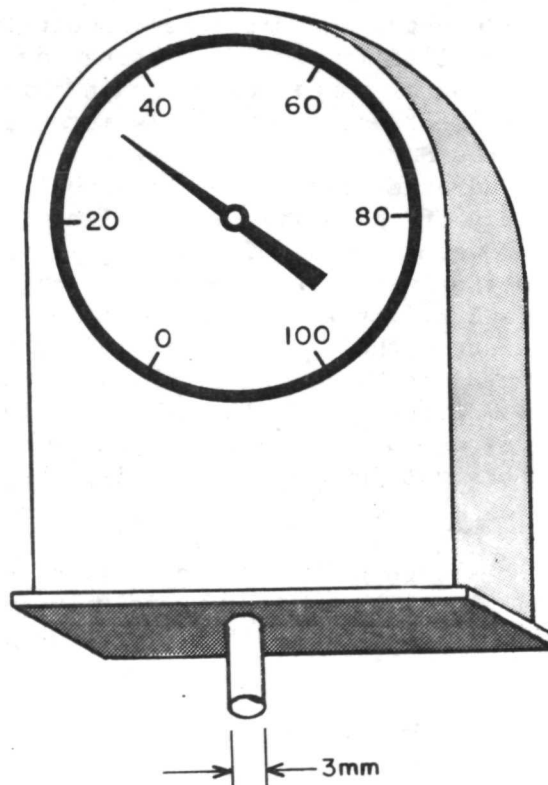


Figure B-6. Hardness Tester.

The Team performed a computer search of the NASA document file on measuring hardness of soft materials such as sponge rubbers and plastics. This search revealed that Mr. John Schell of Marshall Space Flight Center had conducted experiments on a variety of hardness testing techniques that appeared to be applicable to this problem. The Team visited MSFC for discussions with Mr. Schell and discovered that a number of techniques in current use at MSFC were applicable to this problem. Mr. Schell not only indicated the type of instrument required for this purpose, but also, of more importance, indicated the procedures necessary to obtain reproducible results. This information was then relayed to the physician at Tulane University School of Medicine who purchased a special instrument that had been modified for his purposes by Mr. Schell; the physician also incorporated Mr. Schell's suggestions in his testing procedures. The experiments by the physician are currently underway utilizing the NASA techniques, and the results of this experiment will have notable medical significance.

PROBLEM TU-35 *Subcutaneous Temperature and Power Density Measurement in a Microwave Field*

The wide scale use of microwave generating equipment in this country has created a significant level of microwave exposure for the general population. The accepted safe limit for microwave exposure in this country is taken as 10 milliwatts per square centimeter, but it is interesting that the accepted safe exposure limit in the Soviet Union is now 0.1 milliwatt per square centimeter. For this and other reasons, considerable research is underway to determine the adequacy of the United States limit. Part of the difficulty in determining the microwave effects of biological system is caused by the difficulty of making measurements in experimental animals exposed to a microwave field. It is likely that the introduction of an animal into an existing field would disturb the field and in addition the measurement of temperature in an animal is complicated by the fact that the microwave radiation may produce a different heating effect in the temperature sensor than in the experimental animal. A means of making a subcutaneous temperature and power density measurement in a microwave field is required which eliminates the above problems.

An information search has been conducted and a problem statement has been circulated. The problem originator is now evaluating the initial responses from the problem statement circulation.

PROBLEM VAM-12 *Heart Rate Tachometer*

A heart rate measuring device developed for the Skylab program may have uses in clinical medicine. The problem originator is concerned with the problem of assessing the extent of the loss of mental function by persons having experienced brain damage. Patients having suffered brain damage (e.g., a stroke victim) will be subjected to tests in which they are given information at varying rates and are expected to make simple decisions.

For example, the patient may be shown a movie of a series of automobiles passing a certain point and will be required to press a button each time a particular sequence of cars is encountered (e.g., two red cars immediately followed by one blue car). The frame speed of the movie will be increased until the patient experiences difficulty in making decisions. The problem is to find a quantitative measure of the level of difficulty that is experienced by the patient. The error rate is, of course, important but provides insufficient information to adequately determine the point at which decision making becomes particularly stressful. One of the parameters that will provide additional information is heart rate. Heart rate will provide an indication of mental stress and should be responsive to subtle changes in levels of stress. While heart rate can be determined by a number of methods, it is necessary to have a noninvasive technique that will not arouse the awareness of the patient. This research should lead to a clinical method that will be useful in determining the extent of impaired mental function.

A heart rate tachometer that was developed as a possible candidate for monitoring the astronauts' heart rates during the Skylab mission has provided a potential solution to this problem. The proposed system, which was suggested by a Marshall Space Flight Center employee, consists of an ear plethysmograph together with associated tachometer circuitry. The plethysmograph employs a light source that transmit light energy through the ear to a photocell. As the heart beats, the quantity of blood in the ear changes, thus modulating the intensity of the light energy received at the photocell. The tachometer circuitry averages over several heart cycles and produces a voltage output that is proportional to the heart rate in beats per minute. A digital or analog voltmeter is then used for displaying the heart rate. The expected accuracy of the system is ± 1 beat per minute.

The MSFC Technology Utilization Office has arranged for a unit (shown in Figure B-7) to be lent to the problem originator.

OTHER MISCELLANEOUS

PROBLEM EU-12 *A Rapid Method of Applying EEG Electrodes*

A special helmet developed by NASA may prove useful in measuring neurological disorders.

People with neurologic dysfunction represent a significant portion of the patients undergoing rehabilitation in the United States. Neurologic dysfunction can occur as a result of birth defects, disease, or traumatic injury. Emory University Regional Rehabilitation Research and Training Center is active in the rehabilitation of such patients. One of the first things to be determined about such a person is the degree of neurologic dysfunction. One program objective at Emory University Regional Rehabilitation Research and Training Center is to develop techniques to measure the degree of neurologic dysfunction. This information is required at the beginning of treatment because, if the patient cannot process sensory information, there is little hope for rehabilitation.

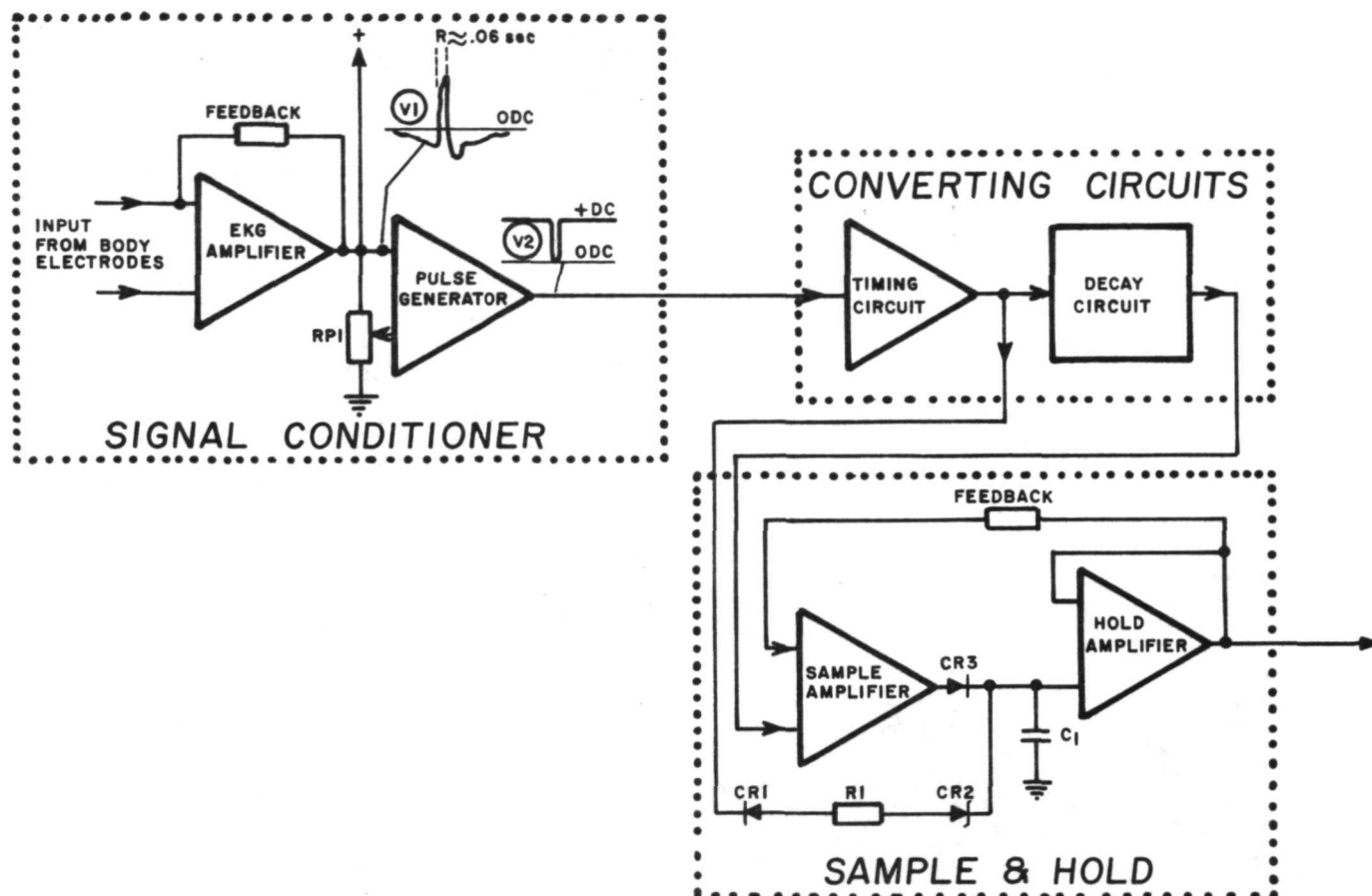


Figure B-7. NASA Cardiometer

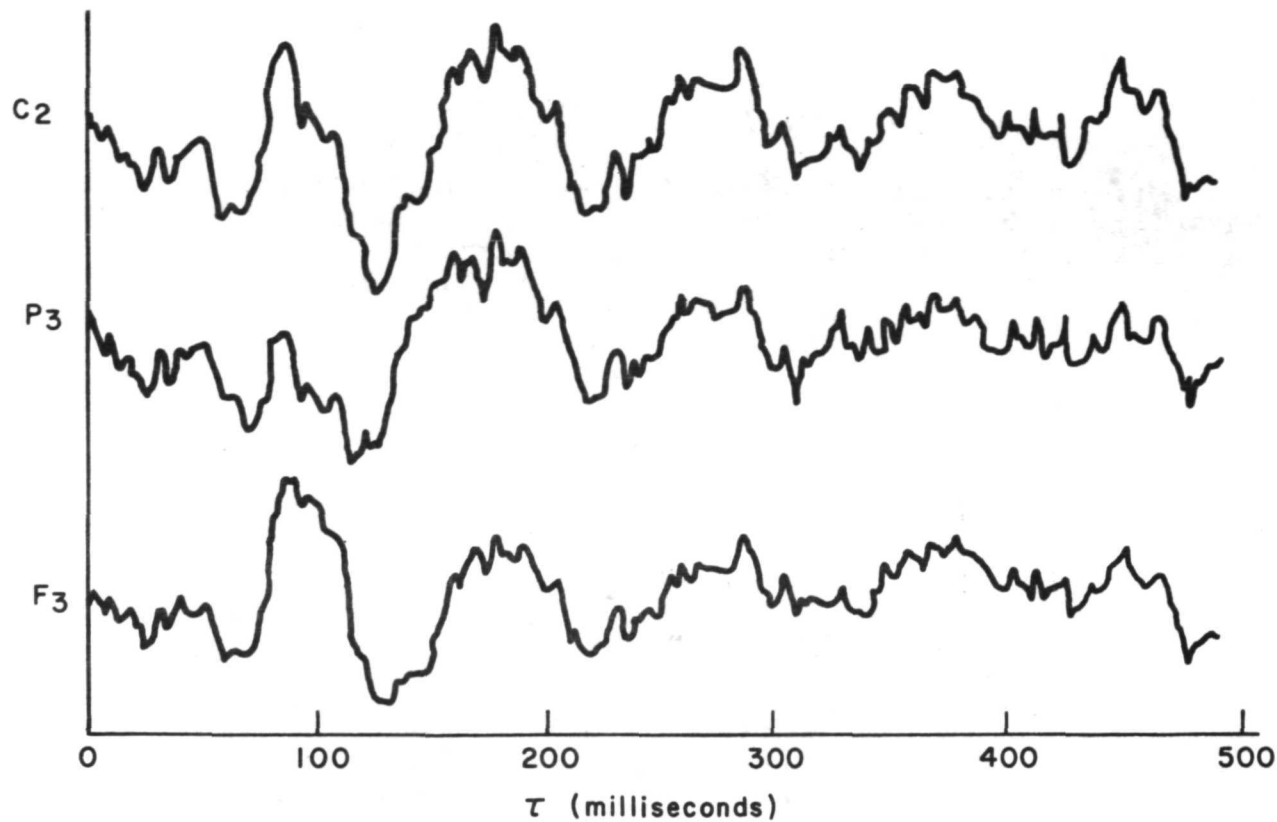
At the present time, evoked responses as measured by electroencephalograms (EEG) are used as an index of dysfunction. In this technique, stimuli of various kinds (auditory, visual, tactile, etc.) are presented to the patient, and the EEG is recorded from electrodes attached to the patient's skull at points appropriate to the type of stimulus. Multiple electrodes are required, varying from 3 to 16, depending on the various circumstances. Attachment of these electrodes by conventional techniques (e.g., collodion) is very time-consuming and frustrating to the patient. It can also be quite alarming to the patient, particularly to one who has received shock therapy.

Severely mentally retarded children present a particular problem. It is desired to employ these techniques to determine neurologic dysfunction in these children, but conventional EEG techniques are impossible with these children. They present very significant problems in handling. They are very difficult to engage in any long-term activity; e.g., it is virtually impossible to persuade such a child to remain seated for the 10 to 15 minutes required to attach the EEG electrodes. In addition, hostile reactions are not infrequent in which the child will reach up and rip an electrode off while another is being applied. As a result, a simpler means of obtaining EEG data is required--specifically, a technique that will permit the installation of electrodes in a very rapid fashion.

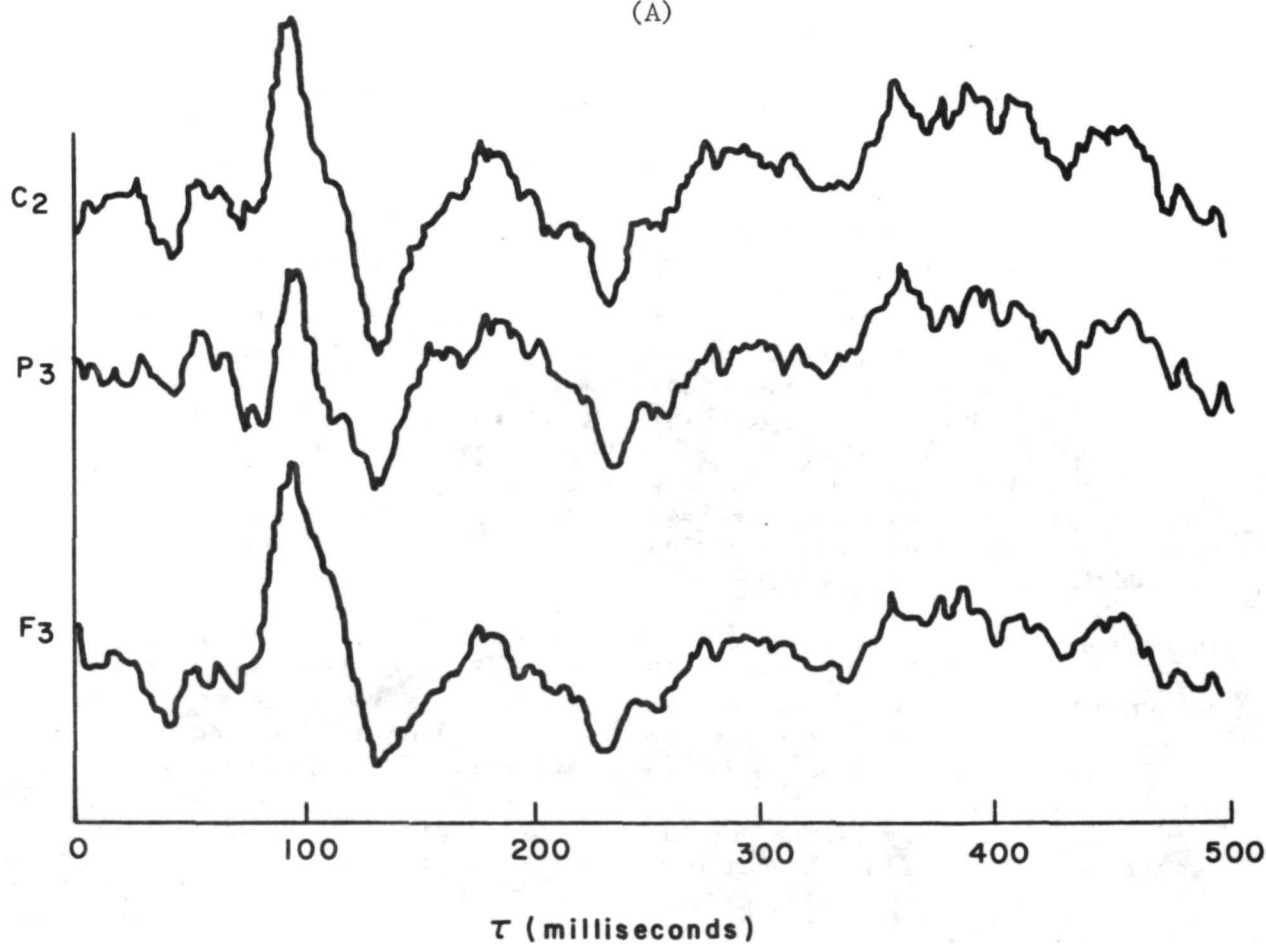
An EEG helmet developed by NASA in the astronaut program was identified as potentially useful in this application. One of the EEG helmets, a three-electrode design, was borrowed from the NASA Biomedical Applications Team at SwRI, which has been modifying the helmet design for civilian biomedical applications. The researcher tested the helmet at Emory University Regional Rehabilitation Research and Training Center using the following procedure.

First, a subject was fitted using EKG solution and conventional silver dish electrodes mounted with collodion. Three electrodes were employed, one each at the C₂, P₃, and F₃ positions, with all signals referred to the left ear. Visually evoked potentials, obtained by using a strobe lamp, were recorded for 200 stimuli. The data were averaged by computer and the average evoked potential for each lead was plotted (See Figure B-8A). The test was repeated using the same electrodes in order to obtain some idea of the variation to be expected with this subject. These data are plotted in Figure B-8B.

The conventional electrodes were removed, the skull carefully cleaned to remove collodion, and the helmet was fitted. Electrode placement was adjusted to obtain, as nearly as possible, the same locations as in the previous trials. The subject was then stimulated using the strobe for 200 flashes as before, and the averaged EEG curve for each lead was plotted (See Figure 9A). Since the electrode conductor in the helmet electrode is actually saline solution, it was decided to inject an excess amount of saline (as might accidentally occur occasionally). Saline was

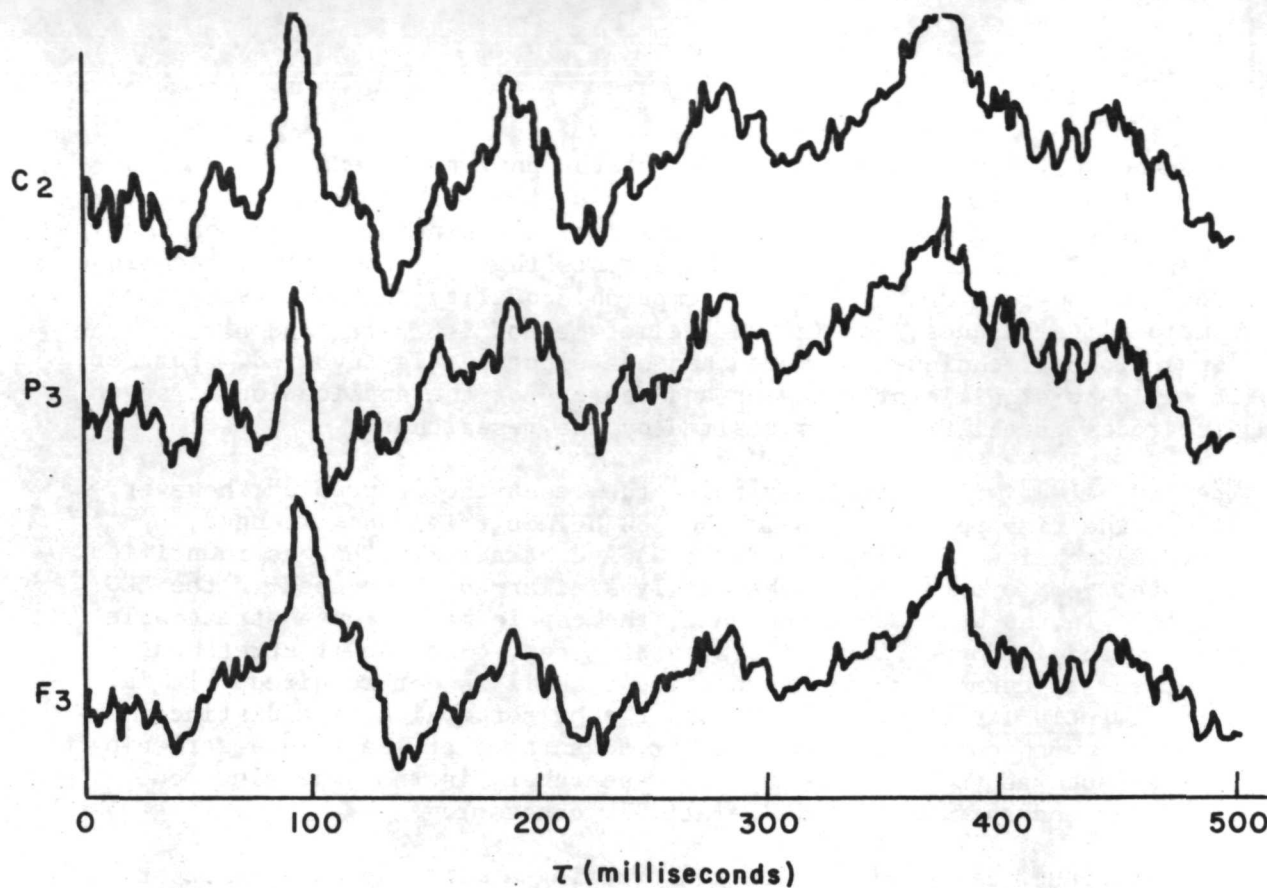


(A)

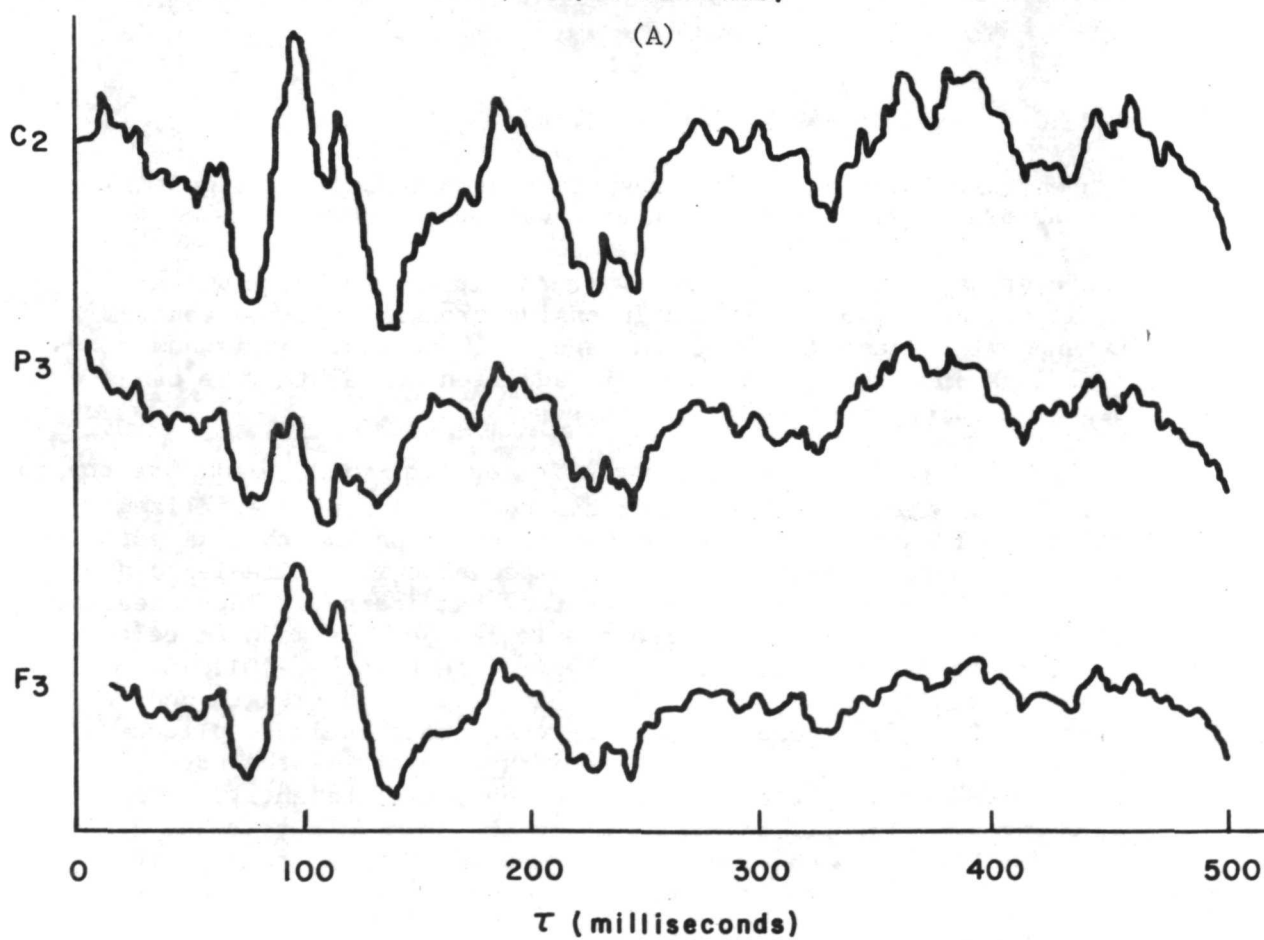


(B)

Figure B-8. Visually Evoked Response with Conventional Electrodes
(Average of 200 Trials)



(A)



(B)

Figure B-9. Visually Evoked Response with EEG Helmet (Average of 200 Trials).

injected until it ran down the sides of the patient's head and the tests were repeated. The data from this test is shown in Figure B-9. It can be clearly seen that excess saline has little observable effect on the records. It was concluded from these tests that (1) the helmet technique provides EEG records that are of comparable quality to those using conventional techniques, and (2) the helmet method is faster and easier than conventional techniques if more than one electrode is involved. Further, it would be significantly faster and easier for the application of seven electrodes on children as is desired by the researcher.

The EEG helmet will definitely solve the researcher's problem; however, during the time period in which the EEG helmet trial was arranged, another technique developed under a NASA contract at UCLA was identified. This unit employs techniques basically similar to those used in the EEG helmet. In the UCLA-developed unit, the cap is made from a stretchable polymer and is donned much like a bathing cap. Because it stretches, electrode adjustment to fit each child's skull is not required. It is significantly lighter in weight than the helmet, which is a distinct advantage with children. One further advantage, at least in a screening program such as that planned by the researcher, is that the electrode positions and spacings remain relatively constant.

The researcher is designing and constructing a soft cap EEG helmet at the present time.

PROBLEM MISC-6 *Motor for Powering Prosthetic Unit*

A small powerful motor developed for space craft may solve a significant problem in a prosthesis for children born without arms and legs.

The researcher is working with a boy 4 years old who was born without arms and legs. With prostheses and intensive training the boy could stand up and walk independently at the age of 19 months. He is now using both legs and arms prostheses. In addition to walking, he can eat, drink, and draw using these prostheses.

The basic problem is to design a prosthetic leg that will permit the boy to go up and down stairs. The researcher has contacted many specialized prosthetics and rehabilitation centers both in Europe and the United States. Unfortunately, little practical experience is available to draw upon in the rehabilitation of one so severely handicapped. The researcher has evolved a design in which the prosthetic legs can be made to telescope by means of a drive motor in the leg. (See Figure B-10). Such a telescoping prosthesis would allow one of the legs to be lengthened to the height of the stair tread so that the other foot could be placed on the next step. The boy would then transfer his weight to the upper leg, and the extended leg would be shortened to the proper height to permit him to stand on the level with both feet on the upper stair tread. The process would then be repeated, thus allowing the boy to traverse the stairs.



Figure B-10. Hydraulic Version of Prosthesis.

The basic problem in the design is to locate a motor that is small and lightweight enough to fit into the prosthetic leg while at the same time powerful enough to lift the entire weight of the boy. Hard and fast specifications on the motor performance are somewhat difficult to assign. As a result, information on the smallest, most lightweight motors that can be obtained and that can provide the power to lift approximately 50 pounds a distance of 8 to 10 inches within a time span of 5 to 10 seconds is desired.

Size and weight are the primary constraints, provided that the motor can produce sufficient power. Because the final design of the prosthesis will be determined by the motor, we hesitate to assign a minimum size and weight. Rather, the smallest, most lightweight motors with adequate power that can be identified will be considered. When this has been established, studies will be made to determine whether the prosthesis design parameters can be modified sufficiently to permit implementation of a prosthesis that the boy can effectively use.

An authority on small motors at Duke University was consulted. He advised us that brushless DC motors designed under NASA contract by Sperry Marine Systems Division to provide motive power in positioning satellite solar panels and unfurling antennas were the most likely to fit this particular application. Information on the motors was obtained from Sperry and forwarded to the problem originator. After reviewing the motor characteristics with his technical staff, the researcher has decided that these motors are well suited for fulfilling the motive function in the prosthesis for the young boy. At the present time, efforts are being made to obtain the motors.

PROBLEM MISC-24 *Metal pH Electrodes*

Shock, a complex self-compounding process that is often encountered, is initiated by many causes. Regardless of the cause, the progression is similar in all cases. Protective mechanisms are set in action that greatly restrict blood flow through peripheral capillary beds. These beds rapidly become hypoxic (lack of oxygen) with a decrease in pH. If untreated, the changes lead to various stages of progressive deterioration from which recovery becomes increasingly difficult. A stage is reached at which treatment is ineffective and death is inevitable.

Early warning of the onset of shock greatly improves the prognosis. The problem originator believes that monitoring of the peripheral pH change can provide this early warning. Unfortunately, commercially available implantable electrodes do not meet the rigors of patient monitoring.

A search of aerospace literature revealed no applicable technology. However, BATeam personnel identified commercially available technology. The problem originator has used this technology to develop prototype electrodes which are now being evaluated.

PROBLEM TU-32 *Calcium Microelectrodes*

The entire class of antibiotic drugs is among the most widely used in modern medicine. Although widely used in the treatment of many diseases such as tuberculosis and urinary infections, dangerous side effects from these drugs can occur. One of these effects is ototoxicity or the loss of hearing due to the drug. Many otherwise useful drugs cannot be used to the extent desired because of the ototoxicity problem. The cause of the ototoxicity is not understood and basic research is underway to determine the origin and cause of the problem. In this research study, the calcium content of individual cells will be analyzed in an attempt to provide a clue to the origin of the problem. It is felt that a change in the calcium level of individual cells is an important aspect of the overall problem.

A microelectrode with a 10-micrometer diameter capable of measuring concentrations as low as 1 millimolar with an accuracy and precision of ± 10 percent is required. The initial study of the NASA literature revealed that a medical investigator at the Ohio State School of Medicine had developed an electrode that may meet the requirements for this problem. The problem originator is planning a visit to the Ohio State School of Medicine to determine the applicability of this new technique to his problem.

PROBLEM UNC-66 *Determining Tissue Perfusion Adequacy*

Patients suffering from vascular disorders often encounter pain when attempting a routine physical activity, such as walking. These symptoms may result from inadequate tissue perfusion. If uncorrected, the prognosis is usually one of progressive immobilization combined with irreversible damage to the affected tissue.

If the cause is vascular blockage, in most cases it can be accurately located and removed or bypassed. This restores the blood flow but not necessarily the tissue perfusion. Physiological control systems allow large portions of the blood flow increase to bypass the nutritional capillary beds. In addition, the tissue deterioration could be too extensive to permit perfusion. In either case, additional corrective action is necessary, preferably before the ongoing surgery is terminated. Unfortunately, the physician does not now have a method for quickly evaluating the adequacy of tissue perfusion. Such a method would save the patient the trauma and expense of additional surgery. It would also provide more effective treatment.

PROBLEM USDA-1 *Detection and Separation of Food and Feed Commodities Contaminated with Carcinogens*

Recent research has shown that certain carcinogenic compounds can occur in foods. One important example of these types of naturally occurring compounds are metabolites of *Aspergillus flavus* or *parasiticus*, which are fungi that may occur in nearly all seeds, e.g., wheat, corn, peanuts, and cottonseed. Metabolic products of these fungi are aflatoxins, which are known to be carcinogenic.

Although aflatoxins are not present in all seeds, their concentration may rapidly increase when infected seeds are exposed to high ambient temperatures and high relative humidities during either the growing process or storage. In addition to being a potential health hazard when human beings consume the contaminated food, some research indicates that contaminated animal feed can result in transmission of the carcinogenic agent to the human by a secondary path. It is for this reason that a major research effort is underway by the United States Department of Agriculture to improve existing methods of eliminating the contaminated seeds before they are processed for various food or feed products.

One of the difficulties inherent in separating seeds is the large volume of seed that must be processed. Thus, a method is needed for detecting low levels of aflatoxin in large volumes of seed. One useful technique appears to be separation on the basis of specific gravity, because contaminated seeds may have a lower specific gravity than noncontaminated seeds. Aflatoxin can be detected by using thin-layer chromatography with a precision of a few parts per billion. The low density seeds have been analyzed using thin-layer chromatography to show the dangerous levels of aflatoxin. Exploratory methods for separating seeds on the basis of density or other physical properties is required.

Separation of seeds by specific gravity (greater than 0.9 and less than 0.9) is required. Large volumes of seed, such as 1,000 tons, can be expected to be received for processing in a single day. A precision of ± 5 percent is desired. Each peanut may weigh from 0.5 to 0.8 grams; each cottonseed from 0.04 to 0.17 grams. It should also be noted that the commercial value of most seeds is low (e.g., raw peanuts approximately \$0.12 per pound; cottonseed \$0.03-0.05 per pound), so that a relatively inexpensive processing cost is required.

A problem statement has been circulated to the NASA field centers.